Executive Summary & Detailed Report

Evaluation of the Indiana Medicaid Preferred Drug List (PDL) Program

Report 2

DATE: 6/30/2005

Presented by:
ACS State Healthcare Solutions

For
State of Indiana
Office of Medicaid Policy and Planning
And
Indiana Medicaid DUR Board

Primary Author:
Michelle Laster-Bradley, Ph.D., M.S., R.Ph. (Project Manager)

Contributors:
Cara Lee, PharmD
Joy McCormick, MBA
Jilka Patel, PharmD
Jim Adkins, M.S., R.Ph.
Christine Klarman, PharmD
Pinkesh Patel, PharmD
Amy Treon, R.Ph.
Ulka Pandya, PharmD, MBA, MHA

TABLE OF CONTENTS

Executive Summary

Introduction

The cost of providing prescription drug services for traditional Medicaid fee-for-service (FFS) recipients has risen dramatically. Nevertheless, the Indiana legislature, the Office of Medicaid Policy and Planning (OMPP), and the Indiana Medicaid Drug Utilization Review (DUR) Board have demonstrated a commitment to address the health care needs for the citizens of Indiana. A major focus for the OMPP and Medicaid DUR Board has been to maximize prescription drug products/services while minimizing the cost to the State of Indiana.

In January 2002, the State of Indiana created a prior authorization (PA) program, the Indiana Rational Drug Program (IRDP), designed to control costs while ensuring appropriate use of prescription drugs for Medicaid recipients. *Indiana Senate Enrolled Act No. 228* (*SEA 228*) of the 2002 General Assembly provided for the creation and implementation of a preferred drug list (PDL) under Indiana Medicaid, with prior authorization for drugs not included on the PDL. The PDL program built upon the intent of the IRDP, but encompassed a much wider range of prescription drug classes. As with the IRDP, the purpose of the PDL is to ensure that Indiana Medicaid recipients receive clinically appropriate prescription drugs, while minimizing the cost incurred. The PDL program was introduced in August 2002 for the Primary Care Case Management (PCCM) Program and the Fee-for-Service Program.

The PDL selection process is based upon a non-biased, clinical review of each medication within a given therapeutic class. The Indiana Medicaid Therapeutics Committee (T Committee) composed of physicians and pharmacists, reviews and submits selection recommendations to the Indiana Medicaid Drug Utilization Review (DUR) Board for approval. In finalizing selection of one or more preferred drugs within a therapeutic class, the T Committee and DUR Board give primary consideration to clinical efficacy or therapeutic appropriateness. Then they consider cost[1], including consideration of the PDL program's cost implications on other components of the State's Medicaid program, such as access to care and potential cost shifting. Medications classified as "nonpreferred" may be permitted upon request from the prescribing physician, using the published prior authorization process.

The Indiana PDL program consisted of 52 therapeutic drug classes implemented over a 13-month period beginning in August 2002. An initial evaluation of the health outcomes and cost implications of the Indiana Preferred Drug List Program was conducted by ACS State Healthcare on prescription and medical data from August 2002 to September 2003 and was submitted to the DUR Board in May 2004.

[1] Cost is net of federal rebates.

After the first year of phased-in implementations of therapeutic classes, a process of continual improvement to the PDL program began in September 2003, with biannual reviews of PDL classes. Report #2, this report, was conducted by ACS for OMPP on prescription and medical data from September 2003 to September 2004, or year 2 of the PDL program. Report #2 is a follow-up evaluation of the health outcomes and cost implications of the Indiana PDL program in its *second year* of operation.

Objectives

The objective of this report is to determine the overall impact of the PDL in accordance with Indiana Code 12-15-35-28(h).

The four primary objectives are to evaluate:

1.) **Any increase in Medicaid physician, laboratory, or hospital costs or in other state funded programs as a result of the preferred drug list.**

2.) **The impact of the preferred drug list on the ability of a Medicaid recipient to obtain prescription drugs.**

3.) **The number of times prior authorization was requested, and the number of times prior authorization was: (A) approved and (B) disapproved.**

4.) **The cost of administering the preferred drug list.**

Results Summary

1.) Impact of the Preferred Drug List on Medicaid Medical Costs

Of the therapeutic classes evaluated (involving 38,724 recipients in Year 1 and 23,585 in Year 2), overall medical expenditures of recipients affected by the PDL program were not associated with any statistically significant differences when compared to recipients not affected by the PDL program (already taking preferred drugs prior to and after PDL implementation). It must be noted that we can only determine association, not causality. This report was not a randomized, controlled design since Medicaid patients were not randomly assigned take preferred or nonpreferred drugs; therefore, only association or lack of association can be determined.

Inclusion/exclusion criteria were applied to all therapeutic classes in the PDL list as shown in Figure E.1.

Figure E.1. Inclusion/Exclusion Criteria for Therapeutic Classes Studied in the Medical Analyses

Therapeutic classes chosen for inclusion in studying medical data were:

- Therapeutic classes with the greatest likelihood of having at least 99% of paid medical claims available for the 6-month period following implementation of the therapeutic class. When using administrative claims databases, the lag time between when a medical service is provided and the time at which a claim for a medical service is entered into the database varies and may be delayed, especially for dual eligible recipients (Medicaid and Medicare). Therefore, only therapeutic classes implemented from August 2002 through December 2002 contained enough post-implementation medical data for study inclusion in Report 1 and the subsequent follow-up in this second report.
- Therapeutic classes with a relatively large market shift to preferred drugs after PDL program implementation. A relatively large market shift was defined as therapeutic classes with 95% or less preferred market share prior to PDL program implementation.
- Therapeutic classes with approved use as long-term maintenance therapy for chronic illnesses. This maintenance therapy criterion allows for a sufficient number of recipients to have taken preferred or nonpreferred drugs for a long, continuous period of time. Long-term maintenance therapy increases the likelihood of detecting an association due to the PDL program and not due to extraneous, unrelated influences.

Therapeutic classes excluded from medical data analyses were:

- Therapeutic classes with greater than 95% preferred drug market share prior to the PDL implementation. These classes were excluded due to an insufficient number of recipients who switched from nonpreferred to preferred in order to detect a change in health status.
- Therapeutic classes approved for short-term therapy or with large seasonal fluctuations in usage (e.g., non-sedating antihistamines). It cannot be determined from prescription claims if a recipient terminated therapy due to decreased symptoms or because the PDL program limited access to the medication. Hence, it would be impossible to determine if medical expenditures are associated with taking or not taking the drugs; and in turn, to determine if taking the drugs for such a short time is associated with medical expenditures.

After applying the inclusion/exclusion criteria, 8 therapeutic drug classes were evaluated for differences in overall medical expenditures and specific medical expenditures: ACE Inhibitors, Alpha/beta Adrenergic Blocker Antihypertensives, Calcium Channel Blocker Antihypertensives, Loop diuretics, Platelet Aggregation Inhibitors, Thiazolidinediones, Triptans, and Proton Pump Inhibitors. Recipients receiving medications from one or more of these therapeutic drug classes were evaluated over a 6-month pre- and a 6-month post-implementation of the PDL program in Report 1. This report, then evaluated those recipients' medical expenditures through the end of Year 2.

Of the therapeutic classes evaluated, the evidence does not demonstrate any statistically significant change in overall medical expenditures. Generally, recipients affected by the PDL program were not associated with a statistically significant difference in overall medical expenditures when compared to recipients not affected by the PDL program. Analyses were performed on specific expenditures and include: prescriber office visits, inpatient hospital admissions, emergency room services, and laboratory procedures. When examining specific medical service types, there is no evidence to suggest that significant cost shifting to other health care providers, laboratories, emergency room services or hospitals is occurring on a wide, systematic scale.

2.) Impact of PDL on Medicaid Recipients' Ability to Obtain Prescription Drugs

Since between 30 to 50% of all patients fail to follow their prescribed therapy once they receive it, noncompliance or lack of persistence with taking medications may be a larger concern. Therefore, analysis examined recipients who were noncompliant (as evidenced by inconsistent prescription claims history) with their medications after receiving non-preferred and preferred medications.

Recipients who were persistent in taking their medications had significantly lower mean expenditures for physician office visits, emergency room visits, and laboratory procedures than recipients who were noncompliant.

The results help illustrate that the problem with recipients health outcomes is not associated with whether recipients are taking nonpreferred or preferred medications, but rather are associated with whether recipients will be compliant with taking *any* medication, whether it is preferred or nonpreferred.

3.) Prior Authorization (PA): Number of Times PA was Requested, Approved and Disapproved.

During the federal fiscal year 2004 (10/1/03 to 9/30/04) there were 75,705 PDL program prior authorizations requested. Of the 75,705 PA's requested, 73,681 were approved (97.3%), 1,177 were disapproved (1.6%) and 847 were suspended (1.1%). The percentage of prior authorizations (PA's) for non-preferred drugs that were disapproved has slightly increased over the two-year span from 0.2% PA's disapproved (between August 2002 to December 2002 when the PDL program first began) to 1.3% PA's disapproved in the first quarter 2005.

Table E.2 Preferred Drug List Prior Authorization Requests

Time Period	Average # Utilizers per Month	Total All PA's Requested	Approved	*% A*	# A PUPM	Denied	*% D*	Sus-pended	*% S*
FFY 2003 (Oct 1, 2002 to Sep 30, 2003)	204,840	80,950	79,200	*97.8%*	0.0322	193	*0.2%*	1,557	*1.9%*
FFY 2004 (Oct 1, 2003 to Sep 30, 2004)	208,995	75,705	73,681	*97.3%*	0.0294	1,177	*1.6%*	847	*1.1%*
Oct 1, 2004 to Mar 15, 2005	205,077	37,893	37,345	*98.6%*	0.0152	477	*1.3%*	71	*0.2%*

4.A) Net Pharmacy Benefit Savings Associated with the PDL Program

Report Period One: 8/1/02 to 7/31/03

The total pharmacy expenditures for the Primary Care Case Management and Fee-For-Service Medicaid program for the annual date of service period of 8/1/02 to 7/31/03 was an estimated $642[2] million (Chart E.1). This figure includes four major categories partitioned by estimated paid amount:

- PDL Applicable – PDL Classes with Potential to Effect Change (24%) = $155 m
- AAAX[3] (considered preferred per statute) (31.1%) = $200 m
- Classes Not Reviewed[4] (27%) = $173 m
- PDL classes with limited[5] benefit @ >95% preferred prior to implementation (18%) = $116 m

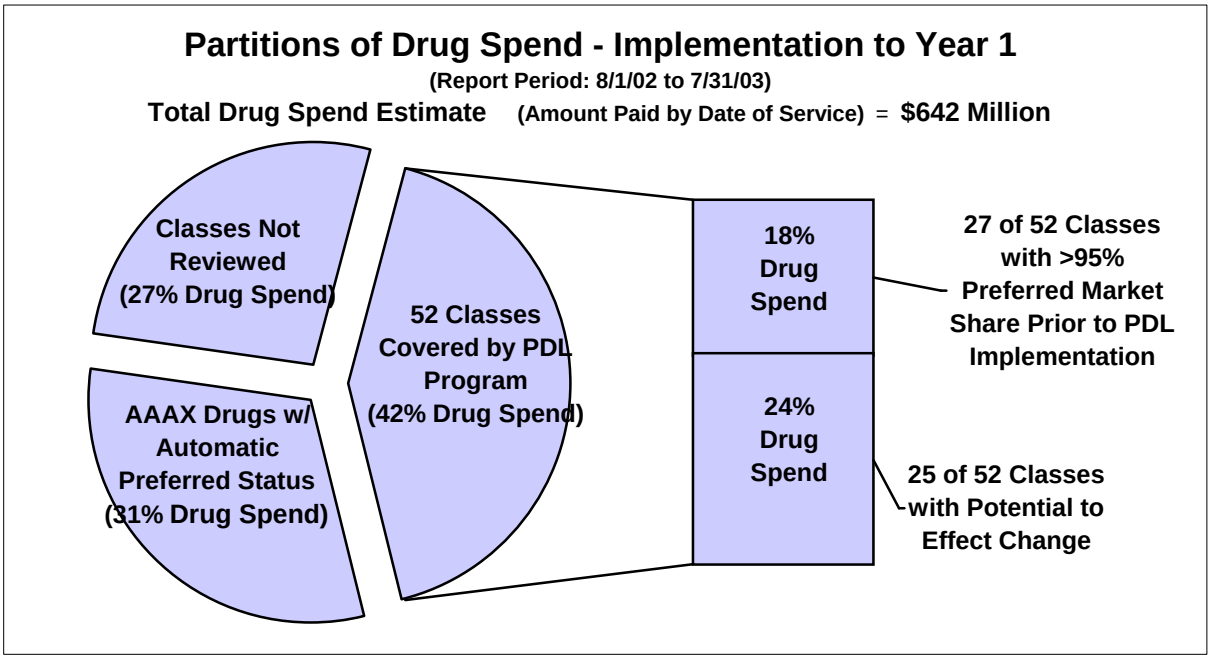

Chart E.1 Partitions of Total Drug Spend ($642 Million) from 8/1/02 to 7/31/03

Source: ACS State Healthcare Analysis of OMPP data.

Total annualized pharmacy benefit net savings (after CMS [standard Federal] rebate deductions and cost to administer the PDL program) from market share shifts in the 52 PDL classes implemented in August 2002 to September 2003 are estimated to be between $7.4 to 8.16 million.

---

[2] Estimates are from 8/1/02 to 7/31/03 claims data by date of service and includes both state and federal share. It does not include rebates Indiana received from drug manufacturers as part of the Medicaid federal rebate program.

[3] These medications are considered preferred per statute – anti-anxiety, antidepressant, antipsychotic and cross-indicated drugs such as: (1) central nervous system drugs, and (2) drugs prescribed for the treatment of a mental illness (as defined by the most recent publication of the American Psychiatric Association's Diagnostic and Statistical Manual of Mental Disorders).

[4] Drug classes of medications not on the PDL program from August 2002 to August 2003.

[5] Over 95% of market share were preferred medications prior to implementation

Report Period Two: Federal Fiscal Year 10/1/03 to 9/30/04

The total pharmacy expenditures for the Primary Care Case Management and Fee-For-Service Medicaid program for the annual date of service period of 10/1/03 to 9/30/04 was an estimated $736[6] million (Chart E.2). This figure includes four major categories partitioned by estimated paid amount:

- PDL Applicable – PDL Classes with Potential to Effect Change (14%) $ 103 m
- AAAX[7] (considered preferred per statute) (35.2%) $257 m
- Classes Not Reviewed[8] (24%) $208 m
- PDL classes with limited[9] benefit @ >95% preferred prior to implementation (26.5%) $196 m

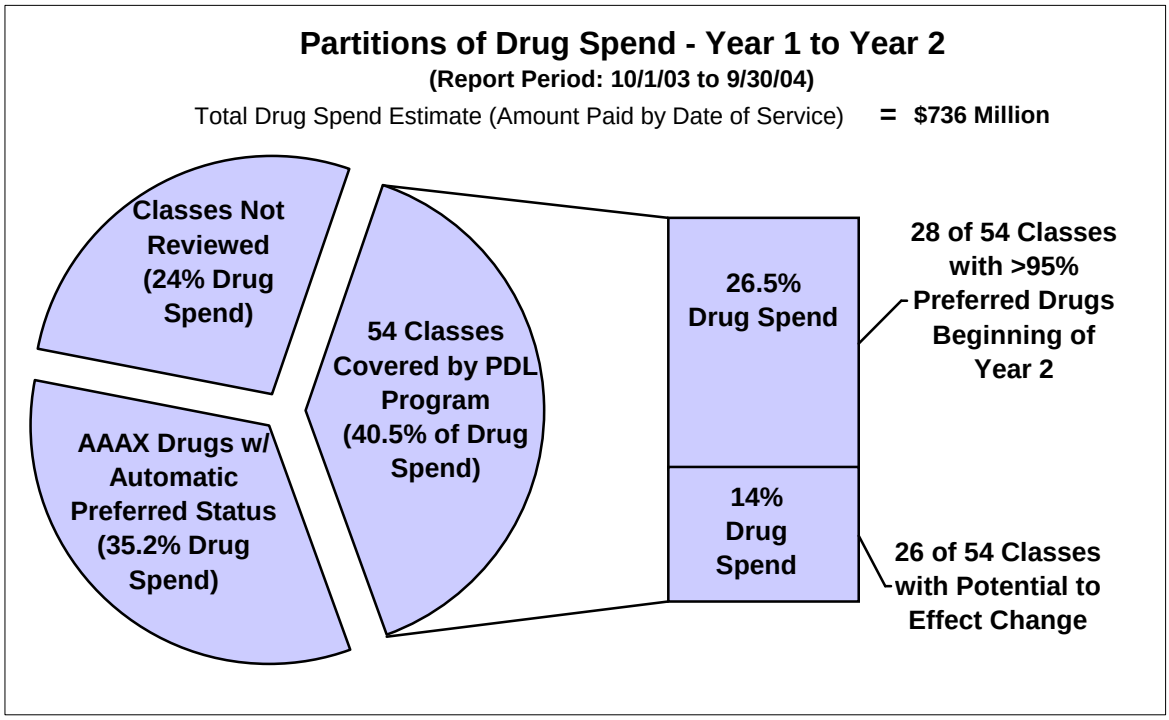

Chart E.2 Partitions of Total Drug Spend ($736 Million) from 10/1/03 to 9/30/04

Source: ACS State Healthcare Analysis of OMPP data.

Total annualized pharmacy benefit net savings (after CMS [standard Federal] rebate deductions and cost to administer the PDL program) due to market share shifts in the 54 PDL classes implemented in August 2002 through September 2004 are estimated to be

[6] Estimates are from 10/1/03 to 9/30/04 claims data by date of service and includes both state and federal share. It does not include rebates Indiana received from drug manufacturers as part of the Medicaid federal rebate program.

[7] These medications are considered preferred per statute – anti-anxiety, antidepressant, antipsychotic and cross-indicated drugs, such as: (1) central nervous system drugs, and (2) drugs prescribed for the treatment of a mental illness (as defined by the most recent publication of the American Psychiatric Association's Diagnostic and Statistical Manual of Mental Disorders).

[8] Drug classes of medications not on the PDL program from October 2003 to September 2004.

[9] Over 95% of market share were preferred drugs at beginning of Year 2.

between $7.40 to 8.16 million in Year 1, and an additional $380,000 to (-$370,000) in Year 2 with two additional classes added to the analysis. Over the two-year PDL

Table E.2 Number of Classes Reviewed and Subsequent Rebate Amounts

Time Period	# Classes Affected by the PDL Program	Total Savings from Market Share Shifts[10] before Rebates	Total Rebate Shifts	Total Net Savings[11] Minus Rebates	Cost of Administering the PDL	Total Net Savings[12] Minus Rebates & Cost of Administering the PDL
Year 1	52	$12,434,379	- $3,524,829	$8,909,550	-$750,000 to -$1,500,000	$8,159,550 to $7,409,550
Year 2	54	$2,060,034	- $ 931,105	$1,128,929	-$750,000 to -$1,500,000	$378,929 to -$370,000
Total				**$10,038,479**	**-$1,500,000 to - $3,000,000**	**$7,038,479 to $8,530,000**

program, the overall net pharmacy savings is estimated to be between **$7.03 million to $8.53 million**.

Number of Classes with Little Opportunity for Market Share Shifts and Subsequent Savings

In 27 of the 52 PDL classes studied in Year 1[13] and in 28 of 54 PDL classes studied in Year 2, preferred drugs selected by the Indiana Medicaid Therapeutics Committee and accepted by the DUR Board did not provide opportunity for either any or very limited market share change because either **all** drugs or => 95% of drugs within the class were selected as preferred. Additionally, 21 of 52 classes in Year 1 and 22 of 54 classes in Year 2 provided very limited potential to shift market share and obtain further savings because utilization in the class was already greater than 95% preferred, but less than 100% preferred.

Table E.3 Number of Classes Reviewed and Percent Preferred – Year 1

# Classes	Year 1 Results	% Before Implementation	% Preferred End of Year 1
52	**TOTAL ALL PDL PROGRAMS**	**75.2%**	**95.8%**
27	Totals for Classes With Only Limited Potential For Market Share Changes (=>95% & including 100%)		
25	Totals for Classes with Substantial Potential For Change (0% to < 95%)		

[10] Estimates include both state and federal share.
[11] Estimates include both state and federal share.
[12] Estimates include both state and federal share.
[13] Two classes in Year 1 were newly implemented and did not yet have enough data for analysis.

Table E.4 Number of Classes Reviewed and Percent Preferred – Year 2

# Classes	Year 2 Results	% Preferred at End of Year 2
54	**TOTAL ALL PDL PROGRAMS at end of YEAR 2**	**93.8%**
28	Totals for Classes With Only Limited Potential For Market Share Changes (>95%)	
26	Totals for Classes with Substantial Potential For Change (0% to< 95%)	

Preferred Drug Market Share Percentage Shifts

Overall, the **preferred drug market share** shifted from approximately **75.2% to 95.8%** during the Year 1 period, then shifted slightly back toward nonpreferred drugs to approximately **93.8%** preferred at the end of Year 2.

Sometimes more expensive PDL drugs were chosen for clinical reasons, based on anticipation of better outcomes. Additionally, some increase in expenditures occurred due to unanticipated rebate or product price changes occurring after the selection of preferred drugs. Expenditures for medications considered preferred per statute – anti-anxiety, antidepressant, antipsychotic and cross-indicated drugs – have not only increased, but also claimed a larger percentage of total drug expenditures from Year 1 to Year 2 (31% to 35.2% respectively).

4.B) Cost to Administer the PDL Program

The time period that is the subject of this PDL Report straddled two (2) contract years because the contract between OMPP and ACS runs concurrent with the State fiscal year (July through June). Although the services provided in each of the contract years were substantially similar, the manner in which the contract price was expressed varied. For the contract year 2003 – 2004, the contract price was expressed as a lump sum while for the contract year 2004 – 2005, the contract price was itemized by service categories. As a result, OMPP has relied on the pricing from the contract year 2004 – 2005 to estimate a range for the costs incurred to administer the PDL Program for year 2. ACS and OMPP have estimated this cost to be between $750,000 and $1.5 million.

Discussion and Conclusions

In response to increases in prescription drug spending and utilization, many public-sector pharmacy benefit programs have been developing and implementing a variety of innovative policy solutions for more effective management of pharmacy benefits. One of the methods that several state Medicaid agencies have implemented is the preferred drug list (PDL) program. The concept behind the PDL program is to improve the quality of pharmaceutical care by ensuring that the most clinically appropriate drug is used, while taking into account the relative costs of the available therapeutically equivalent alternatives. PDL programs may be able to address the problems associated with:

- Recipients who rarely see or pay the true costs of their drugs; and therefore have no incentive to choose less expensive, yet equally effective medications.
- Prescribers who lack current knowledge of the true costs of medications being prescribed.

This evaluation demonstrates that a Preferred Drug List program does decrease net drug expenses; however, the most substantial net savings are realized within the first year of the PDL program when the largest number of recipients shift from nonpreferred drugs to preferred drugs. Furthermore, the market share movement identified through this evaluation suggests that educating prescribers to prescribe and recipients to utilize preferred drugs works. As a result of moving market share to the preferred products, the PDL program produced savings.

Additionally, after following nearly 38,000 recipients in six therapeutic classes for 2-years post-PDL implementation, no evidence was uncovered to suggest an association between the PDL and negative impacts on the quality of care or the ability for recipients to obtain medications. Specifically, there is no evidence at 6-months or at 2-years post-PDL implementation to suggest that significant cost shifting to other health care providers, laboratories, emergency room services or hospitals is occurring on a wide, systematic scale.

Although there were documented savings, these savings may have been lessened by three key factors.

- **Standard federal rebates** – Savings resulting from the PDL policy were reduced after considering the impact of lost CMS federal rebates from some preferred drugs. Higher-priced nonpreferred drugs sometimes had proportionately higher corresponding CMS rebates. When the drugs with higher rebates lose market share under a PDL program, rebate amounts can be reduced.

- **Lack of readily available, timely data for decision support** – Data on relative cost-effectiveness and net cost of drug products, after applying rebates, were not readily available at the beginning of the program. In the past, because each manufacturer applies its rebate after-the-fact, only estimates of the true net cost for drugs can be made until several months after sales are completed. ACS has recently employed modeling tools that now allow for better projections of the cost implications of shifting market share among medications in a PDL therapeutic class.

- **Limits to savings potential**:
  - Some PDL classes had a high percentage of pre-implementation usage of the preferred medications offering little opportunity for savings.
  - Some preferred drugs' net costs were higher than the nonpreferred drugs (chosen on clinical advantage).
  - Some preferred drugs underwent unexpected price increases.

Several solutions have potential to address the reduction of savings from the factors listed above. Savings can best be achieved if a PDL program is combined with methods to increase purchasing power. For example:

- **Limit the number of preferred drugs within a given therapeutic class –** The amount of savings is directly related to the ability to increase the market share of the more favorably priced medication within a therapeutic class. Moreover, the more preferred products, the less opportunity to move market share and therefore less potential for savings. Assuming that medications are clinically equivalent, the smaller the list of preferred drugs, the more potential to move market share and obtain supplemental rebates (discussed below).

- **Add and continue with supplemental rebates** – Savings may be further enhanced when supplemental rebates are obtained as part of the PDL program and are calculated into the PDL savings evaluation. Currently, a supplemental rebates program is in the early stages for Indiana. Supplemental rebates for Medicaid pharmacy claims are a form of state action that increases competition in drug pricing. Increased competition helps drive pricing down in a free market where manufacturers are allowed to set prices in accordance to available competition. In a therapeutic class where numerous brand drugs are found to be clinically equal, supplemental rebates encourage competition by allowing manufacturers to submit progressively higher rebate bids. The manufacturer benefits from obtaining greater market share while the State benefits financially in the form of supplemental rebates. Supplemental rebates cannot be obtained separately from the PDL program. Both the PDL and supplemental rebate programs are needed because without a PDL, there would be no basis for negotiating or the State receiving supplemental rebates on drugs chosen as preferred.

- **Remove "AAAX" drugs from Automatic Preferred Status** – The General Assembly could consider removing automatic preferred status of anti-anxiety drugs, antidepressants, antipsychotics, and cross-indicated drugs that constitute 35.2% (and rising) of the prescription drug budget at the time of this study. The AAAX drugs are quickly gaining an increasing percentage of the prescription drug budget.

- **Broaden scope of class reviews to encompass "Classes Not Reviewed"**

- **Consider fail first PA processes; Fail Preferred agent prior to Non-Preferred Override** – Modify the PA processes to require failure of the preferred drug prior to granting PA approval for the non-preferred drug.

In sum, by limiting the number of preferred drugs within a therapeutic class, choosing less costly preferred drugs, adding supplemental rebates, removing all or some of the "AAAX" drugs from automatic preferred status, and/or broadening the scope of the drug class reviews to encompass the classes not reviewed, the potential for overall savings increases.

METHODOLOGY

CHAPTER 1
Impact of PDL on Health Outcomes of Indiana Medicaid Recipients by Measuring Direct Medical Costs

Overview and Background

Indiana Senate Enrolled Act No. 228 (*SEA 228*) of the 2002 General Assembly provided for the creation and implementation of a preferred drug list (PDL) under Indiana Medicaid with prior authorization for drugs not included on the PDL. The concept behind the preferred drug list program is to ensure that Indiana Medicaid recipients receive the most effective prescription drugs available at the best possible price.

Common opposition to PDL programs has been based upon unsubstantiated allegations that negative health consequences may occur due to changes in medication therapy. The Indiana legislature required the Indiana Office of Medicaid Policy and Planning (OMPP) to determine if the PDL program served its intent of promoting efficacious and safe drug therapy while minimizing the expenditure to the State.

OMPP requires ACS State Healthcare to conduct a study to analyze the Indiana preferred drug list program (PDL) to determine if the PDL results in a negative impact on the health outcomes of Medicaid recipients as well as any cost shifting to other health care providers, laboratory, emergency or hospital services.

This study uses retrospective, paid claims data to evaluate recipient outcomes that may be related to implementation of the PDL program. Any changes in medical utilization or costs for those affected by the PDL program, relative to those not affected, would be *indicators of a possible association* between the PDL program and health outcomes.

Methods

Data

The data for this study were derived from the historical paid claims files from the Indiana Medicaid program. Two sets of data extracts were created and stored on ACS State Healthcare data warehouse for the period of March 1, 2002 to June 30, 2003 and the period of September 1, 2003 to September 30, 2004.

Inclusion and Exclusion Criteria

Inclusion Criteria for Therapeutic Classes of Drugs Studied

Therapeutic classes were included in medical analyses for the first study under the following conditions:

- Therapeutic classes with the greatest likelihood of having at least 99% of paid medical claims available for the 6-month period following implementation of the therapeutic class. When using administrative claims databases, the lag time between when a medical service is provided and the time at which a claim for a medical service is entered into the database varies and may be delayed, especially for dual eligible recipients (Medicaid and Medicare). Therefore, at the time medical data were extracted for the first study in January 2004, only therapeutic classes implemented from August 2002 through December 2002 were considered for inclusion.

- Therapeutic classes with a relatively large market shift to preferred drugs after PDL program implementation. This criterion was defined as drugs with 95% or less preferred drug use prior to PDL program implementation.

- Therapeutic classes approved for use as long-term maintenance therapy for chronic illnesses. This maintenance therapy criterion allows for a sufficient number of recipients to have taken preferred or nonpreferred drugs for a long, continuous period of time. Long-term maintenance therapy increases the likelihood of detecting an association due to the PDL program and not due to extraneous, unrelated influences.

- Only therapeutic classes implemented from August 2002 through December 2002 contained enough post-implementation medical data for study inclusion in Report 1 and the subsequent follow-up in this second report.

Exclusion Criteria for Therapeutic Classes of Drugs Studied

Therapeutic classes are excluded from analyses under the following conditions:

- Therapeutic classes in which greater than 95% of recipients used a preferred drug prior to the PDL implementation. These classes were excluded due to an insufficient number of recipients who switched from nonpreferred to preferred in order to detect a change in health status.

- Therapeutic classes approved for short-term therapy or with large seasonal fluctuations in usage (e.g., non-sedating antihistamines). It cannot be determined from prescription claims if a recipient terminated therapy due to decreased symptoms or because the PDL program limited access to the medication. Hence, it would be impossible to determine if medical expenditures are associated with

taking or not taking the drugs; and in turn, to determine if taking the drugs for such a short time is associated with medical expenditures.

After applying the criteria to the therapeutic classes for the PDL, this study covered recipients receiving medications in the following eight therapeutic classes:

- ACE Inhibitors implemented September in 2002
- Proton Pump Inhibitors implemented September in 2002
- Alpha/Beta Blocker Antihypertensive Drugs implemented in October 2002 (Grouped with Calcium Channel Blockers & Loop Diuretics for analyses)
- Calcium Channel Blocker Antihypertensive Drugs implemented in October 2002 (Grouped with October 2002 Alpha/Beta Blocker for analyses)
- Loop Diuretics implemented in October 2002 (Grouped with October 2002 Antihypertensives above for data analyses)
- Platelet Aggregation Inhibitors implemented in October 2002
- Thiazolidinediones implemented in December 2002
- Triptans implemented in December 2002

Inclusion Criteria for Recipients

Recipients were selected for analysis, if they:

- Had a minimum of 6-months of pre- and 6-months of post- prescription and medical claims history available for Study 1, and two years post- prescription and medical data for follow-up Study # 2.

- Were taking drugs in one of the above therapeutic classes and had at least two PDL-related claims in the three-month period prior to PDL implementation. Recipients of PDL medications were further categorized as Preferred Recipients if at least 80 percent of their PDL-related claims were for preferred drugs; they were Nonpreferred Recipients if at least 80 percent of their PDL-related claims were for nonpreferred drugs. If their usage was mixed – not predominantly preferred or nonpreferred – recipients were excluded from study.

Cohorts

Recipients were categorized by what happened in the three-month period following PDL implementation. There were recipients who: (1) Changed from nonpreferred drugs to preferred, (2) Changed from preferred drugs to nonpreferred, (3) Did not change from a preferred agent, (4) Did not change from a nonpreferred agent, (5) Terminated nonpreferred therapy, and (6) Terminated preferred therapy.

The cohorts of particular interest were:

a. Cohort 1 (Changed Therapy, Persisted Therapy Group): Recipients taking a nonpreferred medication for 6-months before implementation of the PDL list and switched to a preferred medication after PDL program implementation, and persisted with the PDL therapy for up to 2 years through September 2004.

b. Cohort 2 (No Change Group, Persisted on Preferred Therapy): Recipients already taking preferred drugs 6-months both before and after PDL program implementation, and persisted with the preferred therapy for up to 2 years through September 2004.

Recipients with gaps between paid claims in excess of 60 days were excluded from the multivariate analysis of variance (MANOVA) due to the possibility of noncompliance. By definition, recipients with 60-day gaps in paid prescription claims did not utilize Medicaid services for prescriptions and were classified as not having continuous therapy with a drug in one of the therapeutic classes studied. Although patients who may have been non-compliant with their therapy are important, the purpose of this study was to measure the effects of the drugs in the PDL program. So, care was given to our recipient study group to not bias the study with the effects of non-compliance mixed within.

Medical Data Study Period

Analyses of the effects of PDL implementation on medical utilization and costs was limited to certain therapeutic groups where potential changes were most likely to have occurred as a result of PDL implementation. Study period one was 6-months prior to and 6-months after that specific therapeutic class' PDL implementation. Study period two was 12-months post- to two years post-implementation. The month of implementation was excluded in the medical analyses since most implementations occurred mid-month.

Specification of Recipient Outcome Measures

Selected outcomes measures studied are expenditures for physician office visits, emergency room services, laboratory services, and inpatient hospital admissions. Medical outcomes are evaluated 6-months before and after implementation month for each of the two groups of recipients per therapeutic class studied. The month of PDL implementation for the associated therapeutic class was assigned a null period in which no measurements were taken.

Outcome Measure Definitions

Only services related to the disease states treated with the therapeutic class being studied were used in calculating medical expenditures for each service type. This allows a more detailed, narrow scope of expenditures; ensuring that only the expenditures associated with changes in therapy are being included. For example, physician office, lab, or hospital expenditures associated with motor vehicle accidents or broken bones are unrelated to changes in antihypertensive therapy and therefore were not included in measuring expenditure changes between groups. Specific sample sizes, p-values, and observed power for each therapeutic class are reported with each therapeutic class and type of expenditure analyzed.

Inpatient hospital services were measured as a count of each admission date per recipient ID and all expenditures associated with each unique recipient ID per admission date on the inpatient UB-92 claims. Inpatient hospital expenditures were measured only for

services related to the disease state associated with the therapeutic class being studied. For example, when analyzing ACE Inhibitors and Antihypertensives, only the DRG codes for cardiovascular services were measured (see Table 1.1). For thiazolidinediones, expenditures associated with the specific DRG codes for cardiovascular, endocrine, and kidneys were used.

Physician office visits were defined by detail procedure codes associated with outpatient or office services involving physician evaluation and management of patients (shown in Table 1.1).

Table 1.1 Procedure Codes & DRG Codes Used to Define Specific Types of Medical Services Studied

Service Types	Detail Procedure Codes	DRG Codes
Physician Office or Outpatient Visits	99201-99215 99241-99245 99354-99357 99361-99380	N/A
Laboratory Services	80000 – 89999 95250 – glucose monitoring	N/A
Emergency Physician Services	99281-99288	N/A
Services Related to:		N/A
End-Stage Renal Disease & Dialysis	90918- 90999	302-333
Cardiovascular	92950 – 93981 (includes extremity arterial & venous studies)	103-145; 478,479,514-518; 525-527
Endocrine	--	285-301
Pulmonary	94010 - 94799	N/A
Gastroenterology	91000-91299	N/A
Ophthalmology	92002 - 92499	N/A
Allergy & Clinical Immunology	95004 – 95199	N/A

Laboratory services are defined by detail procedure codes in the range: 80000-89999 and 95250 (glucose monitoring). Emergency services are defined by locating the emergency physician services by procedure codes 99281-99288, and then rolling up the costs of all detail numbers associated with those emergency services claims.

Cost Definition

To explore the impact of drug use patterns associated with the PDL program on medical costs, Indiana Medicaid claims were partitioned by type of service. The amount actually paid directly by the Indiana Medicaid program minus recipient co-pays and other insurance was used as the Amount Paid for expenditures. We acknowledge that this definition does not capture the full costs of medical expenditures since Medicare is the primary payer for Medicare-covered services and Indiana Medicaid would pay only the balance. However, this study is only measuring differences in paid amounts between two groups. Since we are only interested in payment changes between groups, we contend that amount paid is sufficient because it applies equally to both groups.

Method of Analysis

Comparison of mean medical expenditures was conducted for all eight therapeutic classes by using MANOVA or a multiple comparisons analysis of variance (ANOVA).

The issue explored was whether recipients affected by the PDL (i.e., those whose medications were changed from nonpreferred to preferred drugs) showed significant mean differences in expenditures compared to those not affected by the PDL (i.e. those who had no change in their medication). If any changes were observed, post hoc multiple comparisons were conducted to determine which group had greater expenditures. Comparing mean expenditures between groups is one way to estimate if there were any detrimental effects to the health of recipients associated with the PDL program. If detrimental effects occurred from the PDL program drug therapy, patients might require greater medical expenditures from increased physician visits, hospitalizations, and lab monitoring procedures.

Results

For recipients taking medications in any of the eight therapeutic classes as a covariate, no statistically significant differences were observed in the overall medical expenditures ($p=0.001$, power=.40) or in specific medical service types ($p=0.006$ MD Paid, 0.072 power; $p=0.003$ ER Paid, 0.225 power; $p=0.002$ Lab, 0.377 power; $p=0.001$ total Medical expenditures, $p=0.402$ power) between the two groups (recipients affected by the PDL program versus recipients not affected). Table 1.2 illustrates the between-subjects effects.

Physician office visit expenditures were the only medical data where a problem was seen. There were many zeroes in the paid amounts that skewed the data causing the Levene's test of equality of error variances to be statistically significantly different. However, a natural log transformation did not help rectify the situation. In looking at the differences between means in physician office visit paid data, there does not appear to be large differences between means. Therefore, this test seems to be robust enough to capture the correct outcomes.

Table 1.2 General Linear Model –ANOVA

(Tests of Between Subjects Effects & Descriptive Statistics)

Tests of Between-Subjects Effects

Source	Dependent Vari	Type III Sum of Squares	df	Mean Square	F	Sig.	Partial Eta Squared	Noncent. Parameter	Observed Power[a]
Corrected Mc	MDPaid	34420941.322[b]	2	17210470.661	38.863	.000	.006	77.726	1.000
	ERPaid	1913238.216[c]	2	956619.108	20.791	.000	.003	41.582	1.000
	LabPaid	1445112.157[d]	2	722556.078	12.843	.000	.002	25.686	.997
	MDEncounterP	989029847.282[e]	2	494514923.641	7.562	.001	.001	15.123	.946
	TotalMedPaid	184569964.684[f]	2	092284982.342	10.369	.000	.002	20.738	.988
Intercept	MDPaid	603530893.418	1	603530893.418	362.836	.000	.092	1362.836	1.000
	ERPaid	28678166.001	1	28678166.001	623.291	.000	.044	623.291	1.000
	LabPaid	53799346.554	1	53799346.554	956.255	.000	.066	956.255	1.000
	MDEncounterP	599028076.651	1	599028076.651	574.766	.000	.041	574.766	1.000
	TotalMedPaid	892584766.026	1	892584766.026	663.542	.000	.047	663.542	1.000
TheraClass6	MDPaid	32260240.354	1	32260240.354	72.847	.000	.005	72.847	1.000
	ERPaid	1887927.811	1	1887927.811	41.032	.000	.003	41.032	1.000
	LabPaid	1443991.906	1	1443991.906	25.666	.000	.002	25.666	.999
	MDEncounterP	987799079.692	1	987799079.692	15.117	.000	.001	15.117	.973
	TotalMedPaid	156091624.662	1	156091624.662	20.597	.000	.002	20.597	.995
Persistence	MDPaid	84543.595	1	84543.595	.191	.662	.000	.191	.072
	ERPaid	66513.086	1	66513.086	1.446	.229	.000	1.446	.225
	LabPaid	152335.971	1	152335.971	2.708	.100	.000	2.708	.377
	MDEncounterP	301357423.954	1	301357423.954	1.525	.217	.000	1.525	.235
	TotalMedPaid	591414928.057	1	591414928.057	2.931	.087	.000	2.931	.402
Error	MDPaid	977136973.448	3497	442849.298					
	ERPaid	621009092.276	3497	46010.898					
	LabPaid	759347578.602	3497	56260.471					
	MDEncounterP	602308778.636	3497	197644091.930					
	TotalMedPaid	488666751.585	3497	201784742.295					
Total	MDPaid	881688044.921	3500						
	ERPaid	763089887.285	3500						
	LabPaid	989758266.125	3500						
	MDEncounterP	056655531.129	3500						
	TotalMedPaid	301442363.652	3500						
Corrected To	MDPaid	011557914.770	3499						
	ERPaid	622922330.492	3499						
	LabPaid	760792690.759	3499						
	MDEncounterP	591338625.918	3499						
	TotalMedPaid	673236716.269	3499						

a. Computed using alpha = .05

b. R Squared = .006 (Adjusted R Squared = .006)

c. R Squared = .003 (Adjusted R Squared = .003)

d. R Squared = .002 (Adjusted R Squared = .002)

e. R Squared = .001 (Adjusted R Squared = .001)

f. R Squared = .002 (Adjusted R Squared = .001)

Estimates

Dependent Variable	Persistence	Mean	Std. Error	95% Confidence Interval	
				Lower Bound	Upper Bound
MDPaid	No Change: PDL before, PDL Persistently to Yr 2	459.066[a]	7.363	444.633	473.499
	NonPDL before, Change to PDL, Persistent with PDL Therapy	464.488[a]	9.661	445.550	483.425
ERPaid	No Change: PDL before, PDL Persistently to Yr 2	100.102[a]	2.373	95.450	104.755
	NonPDL before, Change to PDL, Persistent with PDL Therapy	104.911[a]	3.114	98.807	111.015
LabPaid	No Change: PDL before, PDL Persistently to Yr 2	127.518[a]	2.625	122.373	132.662
	NonPDL before, Change to PDL, Persistent with PDL Therapy	134.795[a]	3.444	128.046	141.545
MDEncounterPaid	No Change: PDL before, PDL Persistently to Yr 2	5857.420[a]	155.558	5552.503	6162.336
	NonPDL before, Change to PDL, Persistent with PDL Therapy	6181.102[a]	204.100	5781.038	6581.166
TotalMedPaid	No Change: PDL before, PDL Persistently to Yr 2	6377.740[a]	157.179	6069.646	6685.833
	NonPDL before, Change to PDL, Persistent with PDL Therapy	6831.185[a]	206.227	6426.952	7235.418

a. Covariates appearing in the model are evaluated at the following values: TheraClass6 = 2.96.

Levene's Test of Equality of Error Variances[a]

	F	df1	df2	Sig.
MDPaid	8.575	1	13498	.003
ERPaid	.284	1	13498	.594
LabPaid	.094	1	13498	.759
MDEncounterPaid	.007	1	13498	.935
TotalMedPaid	.318	1	13498	.573

Tests the null hypothesis that the error variance of the dependent variable is equal across groups.

a. Design: Intercept+TheraClass6+Persistence

Descriptive Statistics

	Persistence	Mean	Std. Deviation	N
MDPaid	No Change: PDL before, PDL Persistently to Yr 2	$470.8451	$679.48317	8465
	NonPDL before, Change to PDL, Persistent with PDL Therapy	$444.6843	$646.12635	5035
	Total	$461.0881	$667.33318	13500
ERPaid	No Change: PDL before, PDL Persistently to Yr 2	$102.9519	$210.53434	8465
	NonPDL before, Change to PDL, Persistent with PDL Therapy	$100.1205	$221.83754	5035
	Total	$101.8959	$214.81577	13500
LabPaid	No Change: PDL before, PDL Persistently to Yr 2	$130.0100	$240.55129	8465
	NonPDL before, Change to PDL, Persistent with PDL Therapy	$130.6057	$232.03119	5035
	Total	$130.2322	$237.40090	13500
MDEncounterPaid	No Change: PDL before, PDL Persistently to Yr 2	$5,970.7773	$14,283.86305	8465
	NonPDL before, Change to PDL, Persistent with PDL Therapy	$5,990.5216	$13,691.72791	5035
	Total	$5,978.1412	$14,065.42695	13500
TotalMedPaid	No Change: PDL before, PDL Persistently to Yr 2	$6,511.4356	$14,283.85947	8465
	NonPDL before, Change to PDL, Persistent with PDL Therapy	$6,606.4110	$14,099.55478	5035
	Total	$6,546.8579	$14,214.95118	13500

Recipients were selected from the newer changes to therapeutic classes in the 2nd year of the PDL program. The conclusion was made that there was not a large enough sample size to follow the medical or prescription data, and that the new recipients would not add anything meaningful if analyzed.

Table 1.3. Recipient Summary Data from PDL Changes in Year 2 of the PDL Program

INDIANA MEDICAID

Participant Counts Involved with Year 2 PDL *Changes* Only in 6 Major Therapeutic Classes

Criteria:
1. If > 65% days supply + minimum days =>59, then labeled as "Preferred" or "Non-Preferred"
2. If < 59 days supply, then labeled as "Insufficient quantity" to determine PDL status
3. If < 65% days supply + minimum days =>59, then labeled as "Mixed PDL/Non-PDL Users"

ACE Inhibitors

Participant ID Count	PRE-PDL Period	Post Period
49	Insufficient Quan	Insufficient Quan
69	Insufficient Quan	PDL
1	Mixed	Insufficient Quan
2	Mixed	PDL
1	NPDL	Insufficient Quan
5	NPDL	PDL
4	PDL	Insufficient Quan
1	PDL	Mixed
2	PDL	NPDL
34	PDL	PDL
168		

ACE Inhibitors with CCB

Participant ID Count	PRE-PDL Period	Post Period
64	Insufficient Quan	Insufficient Quan
2	Insufficient Quan	Mixed
63	Insufficient Quan	NPDL
1	Mixed	NPDL
3	NPDL	Insufficient Quan
14	NPDL	NPDL
1	PDL	Mixed
4	PDL	NPDL
3	PDL	PDL
155		

HMG CoA Reductase Inhibitors

Participant ID Count	PRE-PDL Period	Post Period
31	Insufficient Quan	Insufficient Quan
1	Insufficient Quan	Mixed
30	Insufficient Quan	NPDL
4	NPDL	NPDL
4	PDL	Insufficient Quan
2	PDL	Mixed
4	PDL	NPDL
76		

K+ Sparing Diuretics

Participant ID Count	PRE-PDL Period	Post Period
9	Insufficient Quan	Insufficient Quan
2	Insufficient Quan	Mixed
6	Insufficient Quan	NPDL
3	Insufficient Quan	PDL
20		

B-Blockers

Participant ID	PRE	Post
4	Insufficient Quan	Insufficient Quan
1	Insufficient Quan	Mixed
3	Insufficient Quan	NPDL
2	NPDL	NPDL
2	PDL	NPDL
12		

Conclusion

The Indiana DUR Board and OMPP have demonstrated a commitment to addressing the health care needs of its Medicaid population. OMPP is committed to providing quality health care, while maximizing the financial resources available. The PDL program was implemented to ensure the quality of care and minimize the expenditures to the State of Indiana, while minimizing the impact to recipients and health care providers. As a consequence, OMPP is required to analyze the impact of the PDL program and identify any unintended consequences associated with the PDL program.

In the eight therapeutic drug classes and 38,724 recipients evaluated over both a 6-month pre- and post-implementation of the PDL program, the evidence does not suggest that recipients affected by the PDL (by requiring a change to a preferred medication) have higher medical costs as a result. Following up on the same recipients at one and two-years post-implementation, 23,585 were still eligible for study. In the 23,585 recipients evaluated one-year and two-years post-implementation, the evidence does not support higher cost shifting to other specific medical expenditures, such as increased lab tests.

In conclusion, recipients impacted by the PDL program do not demonstrate a statistically significant increase in medical expenditures when compared to recipients not affected by the PDL program.

Discussion and Limitations

Caution must be used in the interpretation of these results. The following limitations should be noted when evaluating the findings of this section.

Retrospective studies, such as this one, are subject to numerous biases. Since it is impractical to operate a Medicaid program like a controlled clinical trial, there may be differences observed in user groups that are not necessarily attributable to the program itself but to other confounding factors that are difficult to control for or are unknown. For this reason, results of retrospective observational studies such as this one are considered associations and not causal.

Furthermore, the type of statistical tests performed can help account for biases known to be a part of the analyses. The between-group variances were significantly different; meaning, one of the assumptions of ANOVA were violated. Yet, ANOVA is known for being a very robust test. A repeated measures analysis was conducted due to its design advantage in reducing the unsystematic variability in the design and so provides greater power to detect effects. Further analyses using the Bonferroni method were performed to verify results. The Bonferroni method has been shown to be extremely robust and controlled alpha levels and Type 1 error rates best of all the univariate techniques.

In the first study by using medical data that was only 6-months post implementation, Levene's test of equality of error variances was significant for many therapeutic classes and medical service type expenditures, meaning the between-group variances are

significantly different. Levene's test of equality of error variances was most often significant for emergency room services, laboratory, and inpatient hospital services where number of incidences and sample size are low. When sample sizes are low, some recipients in this study may have measurements much different from the average user (outliers) and thus can "skew" the results. The large amount of zero paid amounts for physician office expenditures skewed the data such that even a natural log transformation did not correct the problem. However, the tests used to analyze the data in this study are "robust" as to limit the effect of "skewed" data.

In the follow-up second study, Levene's test was significant only for physician office expenditures. This phenomenon can be explained by the lag time of receiving medical claims data. Having only 6-months post-implementation data for the first study was a significant problem. After two years, gaps in the medical data for 6-month to 1-year post implementation had subsided and increased the validity of the medical data. Since prescription claims data are point-of-sale, there is virtually no lag time on prescriptions claims data. However, medical claims data submission is still paper driven in some offices, and is much slower in getting into the database.

It was mentioned in the first Report that steps should be taken in future studies to equalize the variances through data transformation such as taking the square root of, rate of change of all values of the dependent variable, or removing outliers prior to analyses. Data transformation was recommended for future follow-up studies in Report 1.

There is an apparent selection bias inherent in the two cohorts studied. This means that there are systematic differences in the groups studied based on the way the recipients were selected into the study groups. For example, in some therapeutic classes (or disease states), recipients who were already taking the preferred drugs were stabilized and were inherently using less medical resources both pre- and post-PDL implementation than those in the nonpreferred groups. It would make sense that users of a medication that a therapeutics committee deemed to be clinically superior would have different health outcomes than those who used a "nonpreferred" potentially inferior medication, then switched to the "preferred" medication. Conversely, in some therapeutic classes where the medications were equally effective, recipients switched from a newer, more expensive "nonpreferred" medication may not be as sick as a recipient who has been taking an older, less expensive "preferred" medication for a long time. Thus, the results observed from each therapeutic class studied may not apply to other therapeutic classes.

The medical analyses in this study are based on the paid amounts by the State of Indiana Medicaid Program. Paid amounts (expenditures that the state incurred) are only one measure of costs of providing services. Fluctuations in third party liability (TPL) expenditures and co-pays are not accounted for when using paid amounts. There is also the possibility of missing services performed that have not yet been filed or paid. For these reasons, this study does not capture trends in the total overall expenditures for medical services but rather the State's liability for the services studied.

The 6-month post-PDL study period was a relatively short-term follow-up. Medical illnesses may take longer than 6 months to develop and further follow-up with longer post-periods should be conducted. The two largest limitations to the first study, low power measures in many of the drug classes studied and the highly skewed medical data were rectified with the second iteration of this study, except for specific physician office visits. Any effects of the program became more evident during this subsequent PDL evaluation and we were able to have much more confidence in the statistical results.

CHAPTER 2
The Effects of the Preferred Drug List Program on Medicaid Recipients' Access to Medications

Introduction

Under a PDL program, claims for nonpreferred medications cause a denial edit to post on the dispensing pharmacy's point of service response. This edit directs the pharmacist to contact the prescriber. The prescriber may either instruct the dispensing pharmacist to dispense a "preferred medication," call an ACS consulting pharmacist to discuss alternative therapy, or request prior approval from the Indiana Medicaid program or its contractor to use the originally prescribed "nonpreferred" medication.

Claim denials may also occur if there is an attempt to refill a prescription too early. The prescriber may discuss any of these events with the reviewing pharmacist to arrive at an appropriate course of action. The possible outcomes of denied claim events are: 1) the new prescription is filled without delay, 2) the new prescription is filled after a delay, or 3) no related or follow-up prescription is prescribed.

Concern has been expressed by some patient advocates, manufacturers, prescribers, patients and others that a Preferred Drug List program may cause some patients harm by either causing a delay in starting on prescribed medications or by potentially "restricting access" to medications. Specifically, if pharmacists cannot contact the prescriber and bring resolution to the denied claims rather quickly, patients may leave the pharmacy with no medication. Some patients will eventually receive medications after a delay; while, other patients may choose not to follow-up later thereby, in essence, terminating therapy previously begun, or never starting the drug therapy.

First, not all delays or therapy terminations associated with a PDL program are undesirable. Delays can occur between the time of the denial and the next fill because the participant attempted to receive an early refill. The physician might not have chosen to call for a prior authorization and simply allowed the therapy to terminate because the prescription was no longer necessary. There might have been no follow up prescription filled because the member was no longer eligible for Medicaid.

Second, some delays seen through the prescription claims data are not actually delays in therapy. The physician may have given the recipient prescription samples. Although a delay in the payment for a claim is quantifiable, it is difficult to truly quantify an actual delay in therapy from claims data. A pharmacist may choose to dispense a small supply of denied medication for a recipient until such time that the prescriber requests a prior authorization for the product.

Nevertheless, although it is desirable to increase the share of "preferred" medications versus "nonpreferred" medications, when claims are denied, it is important to enable

participants who need prescribed medications to obtain them while limiting inappropriate use of medications.

Therefore, ACS performed an analysis to determine if the implementation of the Indiana State Medicaid Preferred Drug List (PDL) Program impacted medication access for participants.

Report 1 Review

ACS' claims processing system enabled the identification of denied claims for nonpreferred medications in the preferred drug list. Of the 188,508 monthly recipients followed between May and September 2003, only 4,462 (2.36%) experienced a denied pharmacy claim. Most of these recipients went on to receive the medication through a prior authorization approval. Over half of the follow-up claims were processed on the same day that the denial occurred. Therefore, delays in obtaining medications were a problem for only 1.2% of recipients. Of those recipients experiencing a delay, only 1,485 (0.78%) overall and 0.3% recipients receiving prescriptions for antihypertensives experienced a denied claim with no prior approval of a nonpreferred medication, and no paid claim for a related medication within 30 days. The percent of eligible participants experiencing an exception event, and not receiving a medication within 30 days of the event, ranged from 0.3% for the antihypertensive classes

Further, denials for a given class diminished monthly as providers gained experience with the program. It is impossible to know from pharmacy claims data what portion of these dropped claims were clinically inappropriate to be getting filled anyway, such as duplicate or unnecessary therapies. Overall, the low percentage suggests a minimum impact on PDL users. We do not know how many of the dropped claims were due to medications having no refills left as opposed to being new medications with refills left. While we understand that some dropped claims may have come from medications with no refills, this analysis was not included the study.

Therapy termination was an expected and potentially desirable outcome for the preferred drug list program. The PDL intervention was helpful in flagging cases of inappropriate therapy or therapy that was due to be discontinued. Therefore, some share of those exception events that were without follow up would be appropriate. Again, it was not possible to assess the degree to which exception events with no follow up medication were desirable or were instead the result of recipients, physicians or pharmacists who failed to follow through with their respective responsibilities.

Report 2 Review

Since between 30 to 50% of all patients fail to follow their prescribed therapy[14] once they receive it, noncompliance or lack of persistence with taking medications may be a larger concern. Therefore, Report 2 analysis examined recipients who were noncompliant (as

[14] Amercian Medical Association – Report 2 of the Council on Scientific Affairs, 1998.

evidenced by inconsistent prescription claims history) with their medications after receiving non-preferred and preferred medications.

Methods

For the purposes of studying noncompliance, recipients were classified as follows. Recipients were followed from March 2002 to September 2004. The Indiana Medicaid recipients had an overall rate of noncompliance of 26.4%.

Table 2.1. Sample Sizes

Between-Subjects Factors

		Value Label	N
Persistence	20	No Change, PDL to PDL, Persistent Tx	7198
	21	NonPDL to PDL Change, Persistent PDL Therapy	4259
	30	No Change, Mild NonCompliance	747
	31	NonPDL to PDL Change w/ Mild NonCompliance	400
	90	No Change, PDL to PDL, Severely Not Persistent w/ PDL med	1820
	91	NonPDL to PDL change, Severely not persistent with PDL med	1150

Results

Results showed that even recipients who were classified as "mildly non-compliant" with their medications defined as recipients who missed at least 2 prescriptions of 30-day therapy in the past 12 months were significantly different from recipients who persisted with their therapy. Results also demonstrated that there were no significant differences in whether recipients were previously taking nonpreferred and switched to preferred medications or had been on preferred medications all along (see Chapter 3); however, there were significant differences between recipients who were persistent in taking their therapy and those who were noncompliant (see Table 2.2).

Recipients who were persistent in taking their medications had significantly lower mean expenditures for physician office visits, emergency room visits, and laboratory procedures than recipients who were noncompliant (Table 2.3).

Conclusions

In conclusion, the results help illustrate that the problem with recipients health outcomes is not associated with whether recipients are taking nonpreferred or preferred medications, but rather are associated with whether recipients will be compliant with taking *any* medication, whether it is preferred or nonpreferred.

Table 2.2. MANOVA on Compliance

Tests of Between-Subjects Effects

Source	Dependent Variab	Type III Sum of Squares	df	Mean Square	F	Sig.	Partial Eta Squared	Noncent. Parameter	Observed Power[a]
Corrected Mod	MDPaid	183564588.631[b]	6	30594098.105	49.516	.000	.019	297.097	1.000
	ERPaid	11535275.434[c]	6	1922545.906	31.668	.000	.012	190.009	1.000
	LabPaid	2846671.162[d]	6	474445.194	6.139	.000	.002	36.835	.999
	TotalMedPaid	4778083957.148[e]	6	796347326.191	3.805	.001	.001	22.829	.967
Intercept	MDPaid	1378533125.074	1	1378533125.074	2231.140	.000	.125	2231.140	1.000
	ERPaid	65993909.268	1	65993909.268	1087.053	.000	.065	1087.053	1.000
	LabPaid	83322469.486	1	83322469.486	1078.157	.000	.065	1078.157	1.000
	TotalMedPaid	48374986587.559	1	8374986587.559	708.928	.000	.044	708.928	1.000
TheraClass6	MDPaid	14229582.985	1	14229582.985	23.030	.000	.001	23.030	.998
	ERPaid	1413640.418	1	1413640.418	23.286	.000	.001	23.286	.998
	LabPaid	407434.193	1	407434.193	5.272	.022	.000	5.272	.632
	TotalMedPaid	3681841761.124	1	3681841761.124	17.592	.000	.001	17.592	.987
Persistence	MDPaid	168307855.953	5	33661571.191	54.481	.000	.017	272.404	1.000
	ERPaid	10159820.566	5	2031964.113	33.471	.000	.011	167.353	1.000
	LabPaid	2552353.979	5	510470.796	6.605	.000	.002	33.026	.998
	TotalMedPaid	1536695422.945	5	307339084.589	1.468	.196	.000	7.342	.523
Error	MDPaid	9618232713.298	15567	617860.391					
	ERPaid	945057151.904	15567	60709.010					
	LabPaid	1203054332.983	15567	77282.349					
	TotalMedPaid	58093409022.856	15567	209294880.775					
Total	MDPaid	15509128875.966	15574						
	ERPaid	1229793262.391	15574						
	LabPaid	1587271882.389	15574						
	TotalMedPaid	66005304751.637	15574						
Corrected Tota	MDPaid	9801797301.929	15573						
	ERPaid	956592427.338	15573						
	LabPaid	1205901004.145	15573						
	TotalMedPaid	62871492980.004	15573						

a. Computed using alpha = .05

b. R Squared = .019 (Adjusted R Squared = .018)

c. R Squared = .012 (Adjusted R Squared = .012)

d. R Squared = .002 (Adjusted R Squared = .002)

e. R Squared = .001 (Adjusted R Squared = .001)

Table 2.3. Mean Differences Recipients who fill their medication persistently (Persistent Users) and those who are inconsistent in getting their medications filled (NonCompliant)

Descriptive Statistics

	Persistence	Mean	Std. Deviation	N
MDPaid	No Change, PDL to PDL, Persistent Tx	$553.7238	$705.03821	7198
	NonPDL to PDL Change, Persistent PDL Therapy	$525.7069	$671.53462	4259
	No Change, Mild NonCompliance	$781.7323	$955.08008	747
	NonPDL to PDL Change w/ Mild NonCompliance	$791.5029	$966.33998	400
	No Change, PDL to PDL, Severely Not Persistent w/ PDL med	$768.2491	$1,023.73542	1820
	NonPDL to PDL change, Severely not persistent with PDL med	$786.5029	$1,011.40274	1150
	Total	$605.3638	$793.35345	15574
ERPaid	No Change, PDL to PDL, Persistent Tx	$118.3292	$223.65162	7198
	NonPDL to PDL Change, Persistent PDL Therapy	$115.6212	$237.21147	4259
	No Change, Mild NonCompliance	$181.8547	$299.40468	747
	NonPDL to PDL Change w/ Mild NonCompliance	$190.2817	$329.01114	400
	No Change, PDL to PDL, Severely Not Persistent w/ PDL med	$169.8271	$273.71790	1820
	NonPDL to PDL change, Severely not persistent with PDL med	$171.7533	$295.80007	1150
	Total	$132.4466	$247.84338	15574
LabPaid	No Change, PDL to PDL, Persistent Tx	$149.1504	$253.69882	7198
	NonPDL to PDL Change, Persistent PDL Therapy	$149.8065	$244.64870	4259
	No Change, Mild NonCompliance	$180.1872	$365.92513	747
	NonPDL to PDL Change w/ Mild NonCompliance	$180.2543	$286.57844	400
	No Change, PDL to PDL, Severely Not Persistent w/ PDL med	$167.6293	$356.60837	1820
	NonPDL to PDL change, Severely not persistent with PDL med	$185.8309	$325.05760	1150
	Total	$156.4853	$278.27211	15574
TotalMedPaid	No Change, PDL to PDL, Persistent Tx	$7,490.3659	$14,977.11166	7198
	NonPDL to PDL Change, Persistent PDL Therapy	$7,652.3951	$14,969.60032	4259
	No Change, Mild NonCompliance	$7,410.1710	$11,868.95631	747
	NonPDL to PDL Change w/ Mild NonCompliance	$6,702.5388	$8,601.26253	400
	No Change, PDL to PDL, Severely Not Persistent w/ PDL med	$8,170.2209	$14,749.93520	1820
	NonPDL to PDL change, Severely not persistent with PDL med	$7,829.7778	$11,905.69271	1150
	Total	$7,615.1062	$14,474.84237	15574

CHAPTER 3
Preferred Drug List Program Prior Authorizations

Preferred Drug List (PDL) program prior authorizations (PA's) requested, approved, and denied are listed in the table below. In order to give two different perspectives on the PA's requested for non-preferred drugs, both calendar year and federal fiscal year figures are listed along with partial year data.

During the calendar year 2003 (1/1/03 to 12/31/03) there were 73,251 PDL program prior authorizations requested. Of the 73,251 PA's requested, 71,053 were approved (97.0%), 259 were denied (0.4%) and 1,939 were suspended (2.6%).

During the calendar year 2004 (1/1/04 to 12/31/04) there were 81,440 PDL program prior authorizations requested. Of the 81,440 PA's requested, 79,567 were approved (97.7%), 1,352 were denied (1.7%) and 521 were suspended (0.2%).

The percentage of prior authorizations (PA's) for non-preferred drugs that were approved slightly decreased from 99.5% (between August 2002 to December 2002 when the PDL program first began) to it lowest point of 97.0% in calendar year 2003. The percentage of PA's for non-preferred drugs that were approved increased from it lowest point in calendar year 2003 (97.0%) through calendar year 2004 (97.7%) and into the first quarter 2005 (98.2%).

The percentage of prior authorizations (PA's) for non-preferred drugs that were denied slightly increased over the life of the PDL Program from 0.2% denied (between August 2002 to December 2002 when the PDL program first began) to 1.7% in the first quarter 2005.

Table 3.1. Preferred Drug List Prior Authorizations

Time Period	Total All PA's Requested	Approved	*% A*	Denied	*% D*	Suspended	*% S*
FFY 2003 (Oct 1, 2002 to Sep 30, 2003)	80,950	79,200	*97.8%*	193	*0.2%*	1,557	*1.9%*
FFY 2004 (Oct 1, 2003 to Sep 30, 2004)	75,705	73,681	*97.3%*	1,177	*1.6%*	847	*1.1%*
Oct 1, 2004 to Mar 15, 2005	37,893	37,345	*98.6%*	477	*1.3%*	71	*0.2%*
August 1, 2002 to Dec 31, 2002	17,866	17,775	*99.5%*	91	*0.5%*	0	*0%*
Calendar Year 2003	73,251	71,053	*97.0%*	259	*0.4%*	1,939	*2.6%*
Calendar Year 2004	81,440	79,567	*97.7%*	1,352	*1.7%*	521	*0.6%*
Jan 1, 2005 to Mar 15, 2005	14,003	13,745	*98.2%*	236	*1.7%*	22	*0.2%*

TABLE 3.2

NUMBER OF PRIOR AUTHORIZATIONS
ISSUED BETWEEN AUGUST 2002 AND DECEMBER 2002
BY THERAPEUTIC CLASSES WITH PREFERRED DRUG LISTS IN EFFECT AT THE TIME
WITH COUNT OF DENIALS

PDL Therapeutic Class	Count of PAs Between August and December 2002	Count of Denied PAs	% Denied
	1		0.0%
A4D - ACE Inhibitor	594		0.0%
A4D - ACE Inhibitor W/Diuretics	2		0.0%
A4F - Angiotensin Receptor Blockers	1		0.0%
A4F - Angiotensin Receptor Blockers w/Diuretics	5		0.0%
A4K - ACE Inhibitor w/CCB	16		0.0%
A9A - Calcium Channel Blockers	71		0.0%
C4N - Thiazolidenediones	16		0.0%
D4K - Proton Pump Inhibitors	13,289	90	0.7%
H3F - Triptans	29		0.0%
J5D - Beta Agonists	258	1	0.4%
J7A/B/C - ALPHA/BETA Adrenergic Blockers	1,790		0.0%
M4E - Statins	9		0.0%
M9P - Platelet Aggregation Inhibitors	84		0.0%
P5A - Inhaled Glucocorticoids	97		0.0%
R1M - LOOP Diuretics	22		0.0%
Z2A - Non-Sedating Antihistamines	1,491		0.0%
TOTAL	17,775	91	0.5%

Table 3.3 Calendar Year 2003 PA's Related to the PDL Program

Indiana Medicaid - Preferred Drug List Prior Authorizations

Key: A=Approved D=Denied S=Suspended

Run Date: 5/14/2004

Client ID: INCAID

From 01/01/2003 To 12/31/2003

Therapeutic Class or Preferred Drug Description	A	D	S
ACE Inhibitors	594	1	
ACEI with CCB	191		
ACEI with Diuretics	30		
Angiotensin Receptor Blockers (ARBs)	3,824	5	2
Antidiabetic Agents	672	1	
Antiemetic - Antivertigo Agents	66		
Antifungal Oral	848	1	
Antifungal Topicals	602		
Antipsoriatics	3		
Antiulcer- H Pyloric Agents	168		
Antiviral Anti-herpetic Agents	148		
Antiviral Influenza Agents	429		
ARBs with Diuretics	243	2	1
Beta Adrenergic Blockers	211		
Bile Acid Sequestrants	146	2	
Brand Name Narcotics	466	1	
Brand NSAIDS	6,493	61	992
Calcium Channel Blockers	284		
Cephalosporins	482		
Diflucan 150mg 2 Tablet Limit PDLDIFLUCAN	40		
Duragesic	2,315	4	18
Fibric Acids	84		
Fluoroquinolones	402		
Forteo	59	2	
H2 Antagonists	2,464	11	183
Heparin and Related Products	4		
HMG CoA Reductase Inhibitors	631	2	
Imitrex Tablets Month Limit	51		
Inhaled Glucocorticoids	1,026		
Leukocyte Stimulants	18		
Leukotriene Receptor Antagonists	24		
Long Acting Beta Agonists	239	1	
Loop Diuretics	21		
Macrolides	276		1
Miotics - OIPR	94		
Non-Sedating Antihistamines	1,789	4	
Ophthalmic Antibiotics	368		
Opthalmic Mast Cell Stabilizers	89	1	
Oral Antifungals	49	1	
Otic Antibiotics	55		
Oxycodone and Hydrocodone APAP	145	23	12
Oxycodone IR	109	1	4
Oxycontin	797	2	16
Platelet Aggregation Inhibitors	143		
PROPOXYPHENE WITH APAP	24		
Proton Pump Inhibitors	15,632	12	13
SERMS - Bone Resorption Agents	943	3	2

Page 1 of 2

Table 3.3 – continued –

Indiana Medicaid - Preferred Drug List Prior Authorizations

Run Date: 5/14/2004

From 01/01/2003 To 12/31/2003

Short Acting Beta Agonists	3,049	3	1
Skeletal Muscle Relaxants	945	1	
Smoking Deterrent Agents	73		
Systemic Vitamin A Derivatives	164		
Thiazolidenediones	1,207		3
Triptans	449		
Ultram and Ultracet	1,242	18	137
Urinary Tract Antispasmodics- Antiincontinence	271		
Vaginal Antimicrobials	736	2	
Zithromax Limit - PDLZPAK	112		
Zofran Tablet Limit (10 tablets per Rx)	15		
Sum:	52,054	165	1,385

Page 2 of 2

Table 3.4 Calendar Year 2004 PA's Related to PDL Program

Indiana Medicaid - Preferred Drug List Prior Authorizations

Key: A=Approved D=Denied S=Suspended

Run Date: 3/31/2005
Client ID: INCAID

From 01/01/2004 To 12/31/2004

Therapeutic Class or Preferred Drug Description	A	D	S
ACE Inhibitors	1,469	15	1
ACEI with CCB	105	1	0
ACEI with Diuretics	130	1	0
Acne Agents	7	0	0
Actiq	58	40	0
Agents to treat COPD	28	0	0
Alpha Adrenergic Blockers	75	1	0
Alpha- Beta Adrenergic Blockers	1,248	6	10
Angiotensin Receptor Blockers (ARBs)	4,212	26	31
Antidiabetic Agents	535	3	4
Antiemetic - Antivertigo Agents	83	1	0
Antifungal Oral	812	1	1
Antifungal Topicals	555	4	1
Antipsoriatics	11	0	0
Antiulcer- H Pyloric Agents	376	2	3
Antiviral Anti-herpetic Agents	442	1	3
Antiviral Influenza Agents	151	1	0
ARBs with Diuretics	198	0	2
Benign Prostatic Hypertrophy	51	0	0
Beta Adrenergic Blockers	170	1	0
Beta Adrenergics & Corticosteroids	1,119	1	1
Bile Acid Sequestrants	242	1	0
Bone Formation Stimulating	111	2	0
Brand NSAIDS	1,275	132	157
Calcium Channel Blockers	345	3	0
Calcium Channel Blockers w/HMG CoA Reductase Inh	1	0	0
Carafate (Sucralfate)	197	78	10
Cephalosporins	557	7	1
Cox-2 Inhibitor	6,655	599	86
Diflucan 150mg 2 Tablet Limit PDLDIFLUCAN	2	0	0
Duragesic	308	0	0
Eye Antibiotic- Corticosteroid Combo	307	4	1
Eye Antihistamines	386	5	1
Fibric Acids	977	0	0
Fluoroquinolones	278	1	0
Forteo	136	12	0
Growth Hormones	298	44	6
H2 Antagonists	4	0	0
Hematinics	12	0	0
Heparin and Related Products	27	0	0
HMG CoA Reductase Inhibitors	857	4	6
Imitrex Stat Dose Month Limit	1	0	0
Imitrex Tablets Month Limit	4	0	0
Inhaled Glucocorticoids	641	2	1
Inspra	3	0	0

Page 1 of 2

Table 3.4 -- continued --

Indiana Medicaid - Preferred Drug List Prior Authorizations

Run Date: 3/31/2005
Client ID: INCAID

From 01/01/2004 To 12/31/2004

Ketolides	10	0	0
Lactulose	1	0	0
Leukocyte Stimulants	35	0	0
Leukotriene Receptor Antagonists	3,356	9	10
Long Acting Beta Agonists	176	1	0
Loop Diuretics	97	3	0
Macrolides	169	1	0
Miotics - OIPR	474	1	1
Narcotics	1,348	24	5
Nasal Steroids and Antihistamines	609	3	0
Non-Sedating Antihistamines	6,680	68	25
Ophthalmic Antibiotics	474	1	0
Opthalmic Mast Cell Stabilizers	70	0	1
Oral Antifungals	18	0	0
Other Lipotropics	1	0	0
Otic Antibiotics	350	3	0
Oxycodone and Hydrocodone APAP	10	0	0
Oxycodone IR	2	0	0
Oxycontin	119	0	1
Plan Limits	7,019	49	21
Platelet Aggregation Inhibitors	263	3	7
Prior Authorization	40	1	1
PROPOXYPHENE WITH APAP	1	1	0
Proton Pump Inhibitors	22,895	126	103
SERMS - Bone Resorption Agents	874	2	0
Short Acting Beta Agonists	2,437	8	1
Skeletal Muscle Relaxants	1,538	12	8
Smoking Deterrent Agents	41	0	0
Stadol- NS	5	0	0
Systemic Vitamin A Derivatives	38	0	0
Thiazolidenediones	1,934	18	6
Topical Estrogen Agents	156	3	0
Topical Vitamin A Derivatives	237	2	0
TPL Claim Too Old	332	2	1
TPL Within Filing Limit	28	1	0
Triptans	415	1	2
Ultracet	1	0	0
Ultram and Ultracet	3	0	0
Urinary Tract Antispasmodics- Antiincontinence	442	3	0
Vaginal Antimicrobials	1,396	7	2
Zithromax Limit - PDLZPAK	12	0	0
Zofran Tablet Limit (10 tablets per Rx)	2	0	0
Sum:	**79,567**	**1,352**	**521**

Page 2 of 2

Table 3.5 Partial Year 2005 (January 1, 2005 to March 15, 2005) PA's Related to PDL Program

Indiana Medicaid - Preferred Drug List Prior Authorizations

Key: A=Approved D=Denied S=Suspended

Run Date: 3/31/2005
Client ID: INCAID

From 01/01/2005 To 03/15/2005

Therapeutic Class or Preferred Drug Description	A	D	S
ACE Inhibitors	190	0	0
ACEI with CCB	15	2	0
ACEI with Diuretics	20	0	0
Acne Agents	46	0	0
Actiq	16	4	0
Agents to treat COPD	170	0	0
Alpha Adrenergic Blockers	2	0	0
Alpha- Beta Adrenergic Blockers	291	0	0
Angiotensin Receptor Blockers (ARBs)	750	2	0
Antidiabetic Agents	264	0	1
Antiemetic - Antivertigo Agents	29	0	0
Antifungal Oral	138	0	0
Antifungal Topicals	83	0	0
Antipsoriatics	1	0	0
Antiulcer- H Pyloric Agents	57	0	1
Antiviral Anti-herpetic Agents	127	1	0
Antiviral Influenza Agents	7	0	0
ARBs with Diuretics	41	0	0
Benign Prostatic Hypertrophy	21	0	0
Beta Adrenergic Blockers	18	0	0
Beta Adrenergics & Corticosteroids	134	0	1
Bile Acid Sequestrants	45	0	0
Bone Formation Stimulating	105	0	1
Brand NSAIDS	184	90	1
Calcium Channel Blockers	70	0	0
Calcium Channel Blockers w/HMG CoA Reductase Inh	1	0	0
Carafate (Sucralfate)	24	17	0
Cephalosporins	109	1	0
Cox-2 Inhibitor	644	77	2
Eye Antibiotic- Corticosteroid Combo	72	0	0
Eye Antihistamines	38	1	0
Fibric Acids	95	0	0
Fluoroquinolones	52	0	1
Forteo	43	8	0
Growth Hormones	70	8	1
H2 Antagonists	3	0	0
Hematinics	1	0	0
Heparin and Related Products	4	0	0
HMG CoA Reductase Inhibitors	53	0	0
Inhaled Glucocorticoids	4	0	0
Inspra	5	0	0
Ketolides	79	0	0
Leukocyte Stimulants	3	0	0
Leukotriene Receptor Antagonists	238	1	1
Long Acting Beta Agonists	7	0	0

Page 1 of 2

Table 3.5 -- continued --

Indiana Medicaid - Preferred Drug List Prior Authorizations

Run Date: 3/31/2005
Client ID: INCAID

From 01/01/2005 To 03/15/2005

Loop Diuretics	12	0	0
Macrolides	40	0	0
Miotics - OIPR	73	0	0
Narcotics	256	3	0
Nasal Steroids and Antihistamines	218	1	1
Non-Sedating Antihistamines	1,201	6	2
Ophthalmic Antibiotics	44	0	0
Opthalmic Mast Cell Stabilizers	5	0	0
Other Lipotropics	89	0	0
Otic Antibiotics	17	0	0
Plan Limits	1,694	3	3
Platelet Aggregation Inhibitors	27	0	0
Proton Pump Inhibitors	4,131	10	4
SERMS - Bone Resorption Agents	325	1	0
Short Acting Beta Agonists	278	0	0
Skeletal Muscle Relaxants	318	0	2
Systemic Vitamin A Derivatives	1	0	0
Thiazolidenediones	228	0	0
Topical Estrogen Agents	14	0	0
Topical Vitamin A Derivatives	31	0	0
TPL Claim Too Old	4	0	0
TPL Within Filing Limit	24	0	0
Triptans	49	0	0
Urinary Tract Antispasmodics- Antiincontinence	118	0	0
Vaginal Antimicrobials	179	0	0
Sum:	**13,745**	**236**	**22**

Page 2 of 2

Table 3.6 Federal Fiscal Year 2003 PA's Related to PDL Program

Indiana Medicaid - Preferred Drug List Prior Authorizations

Key: A=Approved D=Denied S=Suspended

Run Date: 3/31/2005
Client ID: INCAID

From 10/01/2002 To 09/30/2003

Therapeutic Class or Preferred Drug Description	A	D	S
ACE Inhibitors	750	0	1
ACEI with CCB	160	0	0
ACEI with Diuretics	20	0	0
Alpha Adrenergic Blockers	7	0	0
Angiotensin Receptor Blockers (ARBs)	3,238	4	2
Antidiabetic Agents	509	1	0
Antiemetic - Antivertigo Agents	41	0	0
Antifungal Oral	693	1	0
Antifungal Topicals	309	0	0
Antipsoriatics	1	0	0
Antiulcer- H Pyloric Agents	54	0	0
Antiviral Anti-herpetic Agents	24	0	0
Antiviral Influenza Agents	3	0	0
ARBs with Diuretics	191	2	2
Beta Adrenergic Blockers	1,976	0	0
Bile Acid Sequestrants	112	1	0
Brand NSAIDS	5,993	47	708
Calcium Channel Blockers	270	0	0
Carafate (Sucralfate)	223	36	56
Cephalosporins	334	0	0
Diflucan 150mg 2 Tablet Limit PDLDIFLUCAN	36	0	0
Duragesic	2,040	4	18
Fibric Acids	25	0	0
Fluoroquinolones	318	0	0
Forteo	31	0	0
Growth Hormones	271	0	12
H2 Antagonists	2,770	10	183
Heparin and Related Products	1	0	0
HMG CoA Reductase Inhibitors	511	0	0
Imitrex Stat Dose Month Limit	16	0	0
Imitrex Tablets Month Limit	40	0	0
Inhaled Glucocorticoids	871	0	0
Lactulose	511	5	102
Leukocyte Stimulants	10	0	0
Leukotriene Receptor Antagonists	7	0	0
Long Acting Beta Agonists	202	1	0
Loop Diuretics	26	0	0
Macrolides	242	0	0
Miotics - OIPR	57	0	0
Narcotics	374	0	0
Nasal Steroids and Antihistamines	1	0	0
Non-Sedating Antihistamines	1,979	0	0
Ophthalmic Antibiotics	178	0	0
Opthalmic Mast Cell Stabilizers	31	0	0
Oral Antifungals	12	0	0

Page 1 of 2

Table 3.6 -- continued --

Indiana Medicaid - Preferred Drug List Prior Authorizations

Run Date: 3/31/2005
Client ID: INCAID

From 10/01/2002 To 09/30/2003

Otic Antibiotics	21	0	0
Oxycodone and Hydrocodone APAP	144	23	12
Oxycodone IR	134	1	4
Oxycontin	674	2	16
Platelet Aggregation Inhibitors	169	0	0
Prior Authorization	36,827	22	283
PROPOXYPHENE WITH APAP	20	0	0
Proton Pump Inhibitors	8,358	10	13
SERMS - Bone Resorption Agents	780	1	2
Short Acting Beta Agonists	2,452	3	1
Skeletal Muscle Relaxants	714	0	0
Smoking Deterrent Agents	66	0	0
Stadol- NS	44	0	3
Systemic Vitamin A Derivatives	84	0	0
Thiazolidenediones	684	0	2
Triptans	369	0	0
Ultracet	14	0	0
Ultram and Ultracet	1,607	18	137
Urinary Tract Antispasmodics- Antiincontinence	209	0	0
Vaginal Antimicrobials	280	1	0
Zithromax Limit - PDLZPAK	72	0	0
Zofran Tablet Limit (10 tablets per Rx)	10	0	0
Sum:	**79,200**	**193**	**1,557**

Page 2 of 2

Table 3.7 Federal Fiscal Year 2004 PA's Related to PDL Program

Indiana Medicaid - Preferred Drug List Prior Authorizations

Key: A=Approved D=Denied S=Suspended

Run Date: 3/2/2005
Client ID: INCAID

From 10/01/2003 To 09/30/2004

Therapeutic Class or Preferred Drug Description	A	D	S
ACE Inhibitors	1,325	16	1
ACEI with CCB	126	1	0
ACEI with Diuretics	104	1	0
Actiq	32	40	0
Alpha Adrenergic Blockers	67	1	0
Alpha- Beta Adrenergic Blockers	931	6	9
Angiotensin Receptor Blockers (ARBs)	3,642	25	28
Antidiabetic Agents	513	2	3
Antiemetic - Antivertigo Agents	83	1	0
Antifungal Oral	768	1	1
Antifungal Topicals	741	4	0
Antipsoriatics	10	0	0
Antiulcer- H Pyloric Agents	414	2	2
Antiviral Anti-herpetic Agents	433	1	2
Antiviral Influenza Agents	546	1	0
ARBs with Diuretics	204	0	1
Benign Prostatic Hypertrophy	18	0	0
Beta Adrenergic Blockers	131	1	0
Beta Adrenergics & Corticosteroids	829	1	1
Bile Acid Sequestrants	182	2	0
Bone Formation Stimulating	73	2	0
Brand NSAIDS	2,375	92	443
Calcium Channel Blockers	351	3	0
Carafate (Sucralfate)	197	82	26
Cephalosporins	553	5	0
Cox-2 Inhibitor	4,687	488	77
Diflucan 150mg 2 Tablet Limit PDLDIFLUCAN	6	0	0
Duragesic	919	1	0
Eye Antibiotic- Corticosteroid Combo	204	4	1
Eye Antihistamines	242	4	1
Fibric Acids	921	0	0
Fluoroquinolones	295	1	0
Forteo	113	11	0
Growth Hormones	289	32	8
H2 Antagonists	3	1	0
Hematinics	13	0	0
Heparin and Related Products	22	0	0
HMG CoA Reductase Inhibitors	820	6	7
Imitrex Stat Dose Month Limit	6	0	0
Imitrex Tablets Month Limit	15	0	0
Inhaled Glucocorticoids	861	2	1
Lactulose	96	1	26
Leukocyte Stimulants	33	0	0
Leukotriene Receptor Antagonists	2,788	8	10
Long Acting Beta Agonists	209	1	0

Page 1 of 2

Table 3.7 -- continued --

Indiana Medicaid - Preferred Drug List Prior Authorizations

Run Date: 3/2/2005
Client ID: INCAID

From 10/01/2003 To 09/30/2004

Loop Diuretics	92	2	0
Macrolides	147	0	1
Miotics - OIPR	356	0	0
Narcotics	1,110	23	3
Nasal Steroids and Antihistamines	262	3	0
Non-Sedating Antihistamines	4,868	67	24
Ophthalmic Antibiotics	592	1	0
Opthalmic Mast Cell Stabilizers	119	1	1
Oral Antifungals	55	1	0
Otic Antibiotics	307	2	0
Oxycodone and Hydrocodone APAP	50	0	0
Oxycodone IR	7	0	0
Oxycontin	357	0	1
Plan Limits	5,244	44	17
Platelet Aggregation Inhibitors	223	3	7
Prior Authorization	113	4	2
PROPOXYPHENE WITH APAP	5	1	0
Proton Pump Inhibitors	22,830	119	124
SERMS - Bone Resorption Agents	809	4	0
Short Acting Beta Agonists	2,723	8	1
Skeletal Muscle Relaxants	1,360	12	7
Smoking Deterrent Agents	43	0	0
Stadol- NS	3	0	0
Systemic Vitamin A Derivatives	116	0	0
Thiazolidenediones	2,013	14	7
Topical Estrogen Agents	116	3	0
Topical Vitamin A Derivatives	164	2	0
Triptans	447	1	2
Ultracet	3	1	0
Ultram and Ultracet	17	0	0
Urinary Tract Antispasmodics- Antiincontinence	371	3	0
Vaginal Antimicrobials	1,510	8	2
Zithromax Limit - PDLZPAK	52	0	0
Zofran Tablet Limit (10 tablets per Rx)	7	0	0
Sum:	**73,681**	**1,177**	**847**

Page 2 of 2

Table 3.8 Partial Federal Fiscal Year 2005 PA's Related to PDL Program

Indiana Medicaid - Preferred Drug List Prior Authorizations

Key: A=Approved D=Denied S=Suspended

Run Date: 3/31/2005
Client ID: INCAID

From 10/01/2004 To 03/15/2005

Therapeutic Class or Preferred Drug Description	A	D	S
ACE Inhibitors	564	0	0
ACEI with CCB	41	2	0
ACEI with Diuretics	58	0	0
Acne Agents	53	0	0
Actiq	42	4	0
Agents to treat COPD	198	0	0
Alpha Adrenergic Blockers	20	0	0
Alpha- Beta Adrenergic Blockers	609	0	1
Angiotensin Receptor Blockers (ARBs)	1,904	5	5
Antidiabetic Agents	449	1	2
Antiemetic - Antivertigo Agents	54	0	0
Antifungal Oral	337	0	0
Antifungal Topicals	190	0	1
Antipsoriatics	4	0	0
Antiulcer- H Pyloric Agents	133	0	2
Antiviral Anti-herpetic Agents	260	1	1
Antiviral Influenza Agents	38	0	0
ARBs with Diuretics	92	0	0
Benign Prostatic Hypertrophy	54	0	0
Beta Adrenergic Blockers	61	0	0
Beta Adrenergics & Corticosteroids	424	0	1
Bile Acid Sequestrants	139	0	0
Bone Formation Stimulating	143	0	1
Brand NSAIDS	435	145	1
Calcium Channel Blockers	149	0	0
Calcium Channel Blockers w/HMG CoA Reductase Inh	2	0	0
Carafate (Sucralfate)	75	31	0
Cephalosporins	261	3	1
Cox-2 Inhibitor	2,614	188	9
Eye Antibiotic- Corticosteroid Combo	175	0	0
Eye Antihistamines	182	2	0
Fibric Acids	210	0	0
Fluoroquinolones	119	0	1
Forteo	94	11	0
Growth Hormones	132	21	1
H2 Antagonists	4	0	0
Hematinics	6	0	0
Heparin and Related Products	12	0	0
HMG CoA Reductase Inhibitors	217	0	1
Inhaled Glucocorticoids	36	0	0
Inspra	8	0	0
Ketolides	89	0	0
Leukocyte Stimulants	13	0	0
Leukotriene Receptor Antagonists	823	2	1
Long Acting Beta Agonists	28	0	0

Page 1 of 2

Table 3.8 -- continued --

Indiana Medicaid - Preferred Drug List Prior Authorizations

Run Date: 3/31/2005
Client ID: INCAID

From 10/01/2004 To 03/15/2005

Loop Diuretics	28	1	0
Macrolides	96	1	0
Miotics - OIPR	229	1	0
Narcotics	586	5	2
Nasal Steroids and Antihistamines	565	1	1
Non-Sedating Antihistamines	3,509	11	3
Ophthalmic Antibiotics	116	0	0
Opthalmic Mast Cell Stabilizers	14	0	0
Other Lipotropics	90	0	0
Otic Antibiotics	94	1	0
Plan Limits	3,469	8	7
Platelet Aggregation Inhibitors	126	0	0
Proton Pump Inhibitors	12,625	23	25
SERMS - Bone Resorption Agents	553	1	0
Short Acting Beta Agonists	824	0	0
Skeletal Muscle Relaxants	728	1	2
Smoking Deterrent Agents	5	0	0
Stadol- NS	2	0	0
Systemic Vitamin A Derivatives	3	0	0
Thiazolidenediones	687	4	1
Topical Estrogen Agents	56	0	0
Topical Vitamin A Derivatives	104	0	0
TPL Claim Too Old	336	2	1
TPL Within Filing Limit	52	1	0
Triptans	125	0	0
Urinary Tract Antispasmodics- Antiincontinence	251	0	0
Vaginal Antimicrobials	521	0	0
Sum:	**37,345**	**477**	**71**

Page 2 of 2

CHAPTER 4
Pharmacy Benefit Expenditure Changes Associated with the Preferred Drug List Program

Introduction

This Chapter explores the economic impact of the Preferred Drug List (PDL) program on the pharmacy benefit component of the Indiana State Medicaid Program. The analysis is based on claims paid August 2002 through September 2003.

The "Methods" section describes how pharmacy reimbursement data is integrated with CMS rebate data to estimate the net cost savings for individual PDL classes, taking into account background variability such as price changes, rebate amount changes and seasonal variation in medication use.

The section on "Factors Affecting PDL Program Savings" highlights the effect of CMS federal rebates, preferred drug selection, shifting market share, and utilization on the net cost savings. The dynamic nature of these factors may impact the various therapeutic classes on the Preferred Drug List in different ways. Therefore, in the section on "Performance of Individual Therapeutic Classes Subject to Preferred Drug List," the performance outcomes and some of the factors that affect the outcomes are summarized.

The "Results" section of this chapter reports the overall preferred drug market share changes, estimated expenditure changes, estimated rebate receipt changes, and estimated net savings experienced by the State. It is important to understand that one consequence of shifting utilization to lower priced medications is a potential reduction in CMS rebates. The CMS rebate reduction can be greater than the expenditure savings for a given therapeutic class.

Since clinical considerations are the primary basis for preferred drug selection, scenarios existed where there are no cost savings associated with choosing a particular drug within a therapeutic class. Drug costs are defined as the price paid to the pharmacy less rebates paid to the State by drug manufacturers. The rebates presently received by Indiana Medicaid are those mandated by the federal government through Centers for Medicare and Medicaid Services (CMS) regulations. Changes in rebate amounts arising from market share shifts to other medications within a class affected net savings to the State.

Extraction of CMS Rebate Data

Rebate data is available in the ACS Data Warehouse. The CMS data provides a unit rebate amount (URA) for each national drug code (NDC)[15], the applicable quarter of service, a termination date if needed, and a load date indicating when the record was loaded into the warehouse. Data loads occur quarterly and often include new records updating the URA for earlier quarters of service.

In order to provide a reasonable basis for estimating the ultimate rebate effect of a PDL, the unit rebate amounts were "fixed" when necessary. The basic file consisted of the latest URA available for each quarter of service that was greater than zero. If there were no values greater than zero for an NDC/quarter of service combination[16], then a value greater than zero for that NDC was borrowed from the nearest adjacent quarter, searching forward and backward. If that method failed to populate the URA cell, then the minimum URA that was greater than zero for that NDC's drug name and quarter of service across all NDCs was used, if one existed. If the value was still zero, then no further effort was made to fix the missing URA value for that NDC/quarter of service combination.

Preferred Drug List Savings Calculations

The method used for estimating PDL savings was based on market share changes for all medications in a therapeutic class covered by the PDL. Market share changes directly affects PDL savings by anticipating *what would have been* spent if no PDL had been implemented *versus what was spent* by having the PDL in place. The method estimated savings for each therapeutic class impacted by the PDL; beginning with the month the therapeutic class was added to the PDL. For each class, month of service, and NDC in the class, the amount paid per claim, the rebate per claim, the net expenditure per claim[17], and the NDC's market share[18] of total claims were calculated for all the drugs in that class. Multiplying each NDC's market share times its average amount (e.g., paid per claim) and then adding those products for all NDCs in the class was how the overall average per claim amounts for each class were calculated. Those average amounts were the "observed" or "actual" average amount paid per claim, average rebate amount per claim and average net expense per claim.

---

[15] NDC refers to the National Drug Code number that uniquely identifies all commercially marketed drug products by their name, strength, package size, delivery route and manufacturer/distributor.

[16] Just over 5 percent of the NDC/month-of-service combinations required for the Indiana study were missing URA values. The missing URAs involved about 4 percent of the claims. The above described search process found appropriate URA values for 90 percent of the claims with missing URAs.

[17] Net expenditure per claim was the amount paid per claim less the rebate amount per claim.

[18] An NDC's market share was the NDC's percentage share of all claims for the medications in the therapeutic class on the PDL in a given month. If, for example, in a month of service, there were 2,500 claims for an NDC and there were 12,000 claims for all the preferred and nonpreferred medications in the NDC's therapeutic class, then the NDC's market share for that month would be 20.6 percent.

Factors Affecting PDL Program Savings

CMS Rebates

CMS rebates have a significant impact on the financial performance of a PDL program. The "Methods" section of this chapter discusses the extraction and use of CMS unit rebate data to estimate potential rebate receipts for all medications in each affected therapeutic class and the "fixes" performed to the CMS data to infer values when they are either missing for a quarter or were clearly erroneous. The volume of claims involved in the "fixes" is small (see "Methods" discussion). These "fixes" enabled us to make reasonable predictions of the amount billed for drugs in a therapeutic class over time. These fixes are conservative, but still may result in modest underestimation of rebate amounts for some therapeutic classes.

Supplemental Rebates

Many Medicaid programs solicited rebates directly from participating manufacturers to supplement the CMS rebates for their preferred drugs. Supplemental rebates enhance the CMS rebates and contribute to additional reductions in the net cost of preferred drugs. These rebates are more stable and could limit the variability associated with the fluctuations of the CMS rebates. However, at the time of this evaluation supplemental rebates had not yet been implemented in the Indiana Medicaid PDL and therefore have no impact on the reported results.

Preferred Product Selection

Preferred drug selections are based on initial comparisons of clinical efficacy and safety, followed by a comparison of the relative economic benefits of the medications in each therapeutic class. Due to superior clinical efficacy, there are times when the selected "preferred" drugs were more costly (had higher prices or significantly lower rebates) than the nonpreferred drugs in the class so that switching to preferred drugs actually increased the State's net cost. The most costly example of this phenomenon was the August 2002 implementation of the nonsedating or minimally-sedating antihistamines where prices increased and rebates were significantly lower than expected. Another example was the Februrary 2003 implementation of the Bone Resorption Suppression Agents.

As noted in the "Results" section, the preferred drug selection process created some PDL classes containing either all preferred drugs, no preferred drugs, or a mix of preferred drugs representing a very high share of the total number of claims in the class. In those situations, there are generally few opportunities to secure positive savings through the shifting of claims volumes to less costly drugs.

Price Changes and Other Cost Factors

As indicated above, a Preferred Drug List program is expected to derive savings by shifting prescribing and utilization habits to preferred drugs. Accordingly, the method used to evaluate savings should capture the effects of market changes while controlling

for other determinants of cost and cost change. Price and rebate changes affect the ACS savings estimates only when they changed the relative net expense of drugs that were being switched from nonpreferred to preferred in a given month. If there were shifts to or from drugs having a month-to-month change in their net cost relative to other drugs in a class, ACS' method would capture the net cost savings/increases associated with movement to the less expensive or more costly drugs. If the drug mix in a therapeutic class remained stable, then changes in ingredient prices, unit rebate amounts or co-payments would not alter the calculated net savings (see "Methods" section).

Inflation, a cause of price change, is an important determinant of pharmacy expenditure growth. The cost-savings methodology used in this report takes into account inflation by estimating net savings based on the average net cost of drugs in a month of service. This methodology does not estimate savings based on any month-to-month change in average expenditure or average rebate which might be due to price inflation or rebate changes generated by manufacturers.

Results

Overall, the PDL program significantly increases the utilization of preferred drugs relative to their nonpreferred alternatives. In January 2002, 7-months prior to PDL implementation and education about the PDL program, **75.2%** of the claims were for preferred drugs. By July 2002, the month preceding implementation of the first therapeutic classes on PDL, the preferred claim-share had already increased to 79%. By September 2003, the preferred claim-share had increased to almost **95.8%** (See Table 4.1). Finally, in September 2004, the preferred claim share had shifted slightly downward **to 93.8%.**

The change in market share shift toward preferred drugs yielded financial benefits for the State of Indiana in both its first and second year of operation.

Year 1. Based on the analysis of the PDL program for 52 classes between August 2002 and August 2003, ACS estimates the total annualized[19] net savings after CMS rebate reductions to be approximately **$8.9 million** (see Table 4.2). The net pharmacy benefit savings represented 4.4% of total net expenditures projected had the PDL program not been instituted.

Year 2. Based on the follow-up analysis of the PDL program for 54 classes between October 2003 to September 2004, ACS estimates the net total annualized[20] net savings after CMS rebate reductions to be approximately $1.12 million (see Table 4.3).

[19] Because different classes had been operational for periods ranging from less than 1 month to just over 13 months at the close of the period studied, the observed results were annualized assuming 12 months of operation for all classes. The expected annual payments/rebates/net expenditures were the values that would have been expected had there been no savings/rebate changes over a 1-year period (e.g., observed payments plus the estimated payment savings for the period).

[20] Because different classes had been operational for periods ranging from less than 1 month to just over 13 months at the close of the period studied, the observed results were annualized assuming 12 months of

TABLE 4.1. Percent Preferred Before and After PDL Implementation

Original Implementation Date	2nd Year Change Date	Ther Class	PREFERRED DRUGS	Jan-02 (Before PDL by 7 months) % Preferred	Sept-03 (End Year 1 of PDL Program) % Preferred	Adjusted Annualized Net Savings Over 1st 12 Months (1st Yr of PDL) (Adjusted Annualized Net Savings minus Fed. Rebate)	Sept/Oct 04 (End Year 2 of PDL Program) % Preferred	Adjusted Annualized Net Savings Over 2nd 12 Months (2nd Yr of PDL) (Adjusted Annualized Net Savings minus Fed. Rebate)	Annualized Amount Paid Total Prior to Rebates	% Preferred Change from Year 1 to Year 2 (negative means lost preferred market share from Year 1)
Aug-02	Oct03, Jun04	Z2A	Z2A - Non-Sedating Antihistamines	24.3%	93.7%	(766,838.25)	94.1%	$2,263,851	$12,792,012	0.4%
Sep-02	Oct03, Jul04	A4D	A4D - ACE Inhibitor	33.1%	98.5%	51,543.55	97.5%	$63,051	$4,487,225	-1.0%
	Sep03, Apr04, Jul04	D4K	D4K - Proton Pump Inhibitors	34.9%	82.4%	6,214,934.91	73.7%	($567,862)	$27,441,018	-8.8%
Oct-02		J7ABC	J7A/B/C - ALPHA/BETA Adrenergic Blockers	94.2%	93.5%	(61,640.62)	99.8%			
	Mar-04		J7A - ALPHA/BETA Adrenergic Blockers				100.0%	($4,493)	$1,946,456	
	Oct-03		J7C - BETA Adrenergic Blockers				99.9%	($25,723)	$4,251,595	
	--		J7B - ALPHA Adrenergic Blockers				99.5%	$1,777	$196,361	6.3%
	--	A9A	A9A - Calcium Channel Blockers	94.0%	97.6%	(86,178.42)	98.2%	($29,766)	$10,546,741	0.5%
	--	R1M	R1M - Loop Diuretics	93.1%	99.0%	6,799.96	99.8%	($4,197)	$2,092,918	0.8%
	--	M9P	M9P - Platelet Aggregation Inhibitors	90.1%	100.0%	(160,561.02)	98.4%	($13,781)	$12,192,138	-1.7%
Dec-02	Oct-03	C4N	C4N - Thiazolidenediones	52.5%	90.1%	713,168.64	98.7%	($121,660)	$10,005,660	8.7%
	Jul-04	A4D	A4D - ACE Inhibitor W/Diuretics	21.8%	90.0%	(2,602.00)	87.8%	$1,778	$474,777	-2.3%
	Oct-03	A4F	A4F - Angiotensin Receptor Blockers w/Diuretics	50.7%	95.0%	35,170.70	93.1%	$8,798	$1,713,257	-1.9%
	Oct-03	A4K	A4K - Ace Inhibitor w/CCB	95.2%	99.0%	(32,358.44)	100.0%	$1,984	$1,379,662	1.0%
	Oct03,Mar04 May04	M4E	M4E - Statins	99.0%	99.6%	(340,978.41)	100.0%	($25,315)	$27,053,472	0.4%
	Apr-04	H3F	H3F - Triptans	56.1%	93.4%	200,335.05	92.2%	($10,884)	$2,310,830	-1.2%
	Oct03, Jul04	Q9B	Q9B - Benign Prostatic Hypertrophy Agents	100.0%	98.9%	(4,546.86)	98.8%	($691)	$1,808,520	-0.1%
	Oct03, Apr04	J5D	J5D - Beta Agonists	85.4%	96.0%	1,204,858.72	95.2%	$296,897	$9,828,446	-0.8%
	--	P5A	P5A - Inhaled Glucocorticoids	77.5%	97.7%	100,611.16	93.1%	$3,897	$6,609,036	-4.6%
	Apr-04	Q7E/P	Q7E/P - Nasal Anti-histamine/Anti-inflammatory Steroids	100.0%	100.0%	(5,285.25)	97.5%	($3,718)	$4,410,943	-2.5%
	--	Z4B	Z4B - Leukotriene Receptor Antagonists	99.8%	99.9%	(20,573.18)	100.0%	$476,326	$32,682,425	0.1%
Jan-03	Mar-04	A4F	A4F - Angiotensin Receptor Blockers	45.7%	88.5%	5,100.34	85.8%	($1,146)	$1,983,049	-2.7%
	May-04	W1WXY	W1W/X/Y - Cephalosporins	71.7%	99.4%	450,721.61	91.0%			-8.4%
		W1WXY	W1W - Cephalosporins				99.8%	($776)	$1,121,164	
			W1X - 2nd Gen Cephalosporins				96.9%	$21,949	$605,519	
			W1Y - 3rd Gen Cephalosporins				76.3%	($39,268)	$2,818,778	-8.3%
	--	W1D	W1D - Macrolides	99.7%	100.0%	(45,111.79)	96.7%	($31,765)	$4,704,570	-3.3%
	Oct03, Sep04	W1Q	W1Q - Fluoroquinolones	100.0%	100.0%	33,477.28	97.9%	($213,557)	$6,388,476	-2.1%
	Apr-04	W3B	W3B - Antifungals	87.4%	94.7%	408,366.70	92.5%	($1,910,968)	$2,530,547	-2.2%
Feb-03	Oct03, Jul04	H6J	H6J - Antiemetic/Antivertigo Agents	96.2%	99.0%	70,323.08	98.4%	($68,242)	$3,404,555	-0.6%
	--	M9K	M9K - Heparin and Related Products	92.3%	89.0%	(316,946.25)	99.8%	$1,520,082	$3,346,150	10.7%
	Jul-04	P4L	P4L - SERM's/Bone Resorption Suppression Agents	62.5%	95.6%	(166,722.99)	93.4%	($12,038)	$7,837,621	-2.2%
May-03	Oct03, Jul04	C4K/L/M	C4K/L/M - Antidiabetic Agents	99.1%	99.9%	(18,101.69)	98.8%	($102,582)	$7,096,763	-1.1%
	--	D7L	D7L - Bile Acid Sequestrants	50.6%	71.2%	25,373.09	72.2%	$14,737	$250,538	1.0%
	Apr-04	H3A	H3A - Brand Name Narcotics	89.3%	98.1%	279,897.57	98.4%	($330,671)	$36,088,507	0.3%
	--	H6H	H6H - Skeletal Muscle Relaxants	54.6%	95.6%	381,280.18	93.7%	($73,697)	$4,176,686	-1.9%
	--	M4E	M4E - Fibric Acids	90.9%	95.4%	(98,801.99)	95.2%	$43,340	$2,306,332	-0.2%
	Mar-04	R1A	R1A - Urinary Tract Antispasmodic/Anti Incontinence Agent	75.7%	98.3%	586,603.33	97.7%	($44,670)	$6,166,399	-0.6%
Jul-03	--	J3A	J3A - Smoking Cessation	69.8%	85.1%	28,877.34	84.8%	($9,744)	$798,560	-0.4%
	Oct03, Jul04	L1B	L1B - Systemic Vit A Derivatives	79.0%	81.8%	(1,330.08)				
		L9B	L9B - Topical Vitamin A Derivatives	97.9%	99.3%	(13,515.48)				
		L1B/5H/9B	L1B/L5H/L9B - Acne Agents (Age 25 and under)				88.8%	$19,305	$705,976	
		L1B/5H/9B	L1B/L5H/L9B - Acne Agents (over 25)				0.0%	($75,700)	$699,809	-1.7%
	Jul-04	L5F, L1A	L5F - Antipsoriatics	55.1%	62.3%	9,827.40	100.0%	($7,869)	$483,398	37.7%
	--	N1B	N1B - Hematinics	100.0%	93.8%	(164,984.36)	100.0%	$42,735	$7,654,848	6.2%
	--	N1C	N1C - Leukocyte Stimulants	80.0%	95.7%	175,583.46	83.9%	($18,367)	$1,252,066	-11.8%
	--	P4B	P4B - Bone Formation Stimulating Agents	0.0%	0.0%	$0	0.0%	$0	$631,913	0.0%
	Mar04, Apr04, Jul04	Q6G	Q6G - Miotics/Other intraocular Pressure Reducers	64.7%	75.5%	(82,448.16)	79.6%	($6,787)	$2,565,907	4.1%
	--	Q6I	Q6I - Eye Antibiotic/Corticosteroid Combos	14.4%	70.4%	(11,003.97)	76.0%	($3,958)	$91,520	5.6%
	Jul-04	Q6R	Q6R - Eye Antihistamines	99.8%	100.0%	17,824.12	98.9%	($3,696)	$300,017	-1.1%
	Oct-03	Q6U	Q6U - Ophthalmic Mast Cell Stabilizers	20.7%	40.7%	(6,623.87)	42.4%	($366)	$128,023	1.7%
	Oct03, May04	Q6W	Q6W - Ophthalmic Antibiotics	94.3%	83.7%	(18,499.42)	98.2%	($101,146)	$682,031	14.5%
	May-04	Q8W	Q8F/W - Otic Antibiotics	97.6%	97.9%	(42,935.95)	99.2%	$33,215	$942,401	1.3%
Aug-03	--	D4F	D4F- Anti-ulcer/H.Pylori Agents			11,185.20	0.0%	$3,859	$21,614	0.0%
	--	Q4F	Q4F - Vaginal Antimicrobials	8.7%	59.3%	76,684.93	67.1%	($403)	$58,480	7.8%
	Apr-04	Q4K	Q4K - Topical Estrogen Agents	100.0%	100.0%	(7,353.26)	82.0%	($2,350)	$215,240	-18.0%
	May-04	Q5F	Q5F - Topical Antifungal Agents	64.0%	92.6%	49,135.59	83.6%	$18,217	$2,150,110	-9.1%
	Oct-03	W5A	W5A - Anti-Herpetic Agents	41.7%	51.6%	247,807.66				
	Apr-04	W5A	W5A - Influenza Agents	0.0%	0.0%	0.00				
		W5A/H6A	W5A - Anti-Herpetic & Influenza Agents				96.0%	($33,673)	$1,621,203	44.4%
Sep-03	Jul-04	S2B	S2B - Cox II's	0.0%	0.0%		0.0%	$199,691	$11,892,289	0.0%
May-04	May-04	R1H	R1H - Inspra (Step Edit: Requires prev.tx w/ spironolactone	N/A	N/A		100.0%	($5,031)	$656,763	
Total		52	**TOTAL ALL PDL PROGRAMS**	**75.2%**	**95.8%**	**$8,909,550**	**93.8%**	**$1,128,929**	**$298,601,311**	**1.1%**

operation for all classes. The expected annual payments/rebates/net expenditures were the values that would have been expected had there been no savings/rebate changes over a 1-year period (e.g., observed payments plus the estimated payment savings for the period).

TABLE 4.2. Year 1 Estimated Annualized Savings Analysis – Detailed Report by PDL Class

ANNUALIZED PROGRAM PERFORMANCE BY THERAPEUTIC CLASS WITH PREFERRED DRUG LIST
SHOWING PAYMENT AND REBATE AMOUNTS

		Total Estimated Savings/Changes Over Twelves Months of Full Operation			Estimate of What Expected Total Claim Counts, Payments, Rebates and Net Expenses Would Have Been Over Same Twelve Months If Program Had Not Been In Operation				Estimated Annual Savings/Changes As Percent of Expected Total		
Implementation Date	Therapeutic Class	Payment Savings	Rebate Changes	Net Expense Savings	Expected Annual Claims	Expected Annual Payments	Expected Annual Rebates	Expected Annual Net Expenses	Payment Savings	Rebate Changes	Net Expense
++8/21/2002	Z2A - Non-Sedating Antihistamines	$ 796,552	$ (1,563,391)	$ (766,838)	228,199	$ 13,808,062	$ 4,542,696	$ 9,265,366	5.8%	-34.4%	-8.3%
9/17/2002	A4D - ACE Inhibitor	$ 239,540	$ (187,996)	$ 51,544	276,378	$ 7,933,106	$ 1,712,045	$ 6,221,061	3.0%	-11.0%	0.8%
9/17/2002	D4K - Proton Pump Inhibitors	$ 6,543,025	$ (328,090)	$ 6,214,935	265,472	$ 34,874,568	$ 9,041,588	$ 25,832,980	18.8%	-3.6%	24.1%
***10/9/2002	A9A - Calcium Channel Blockers	$ 2,814	$ (88,992)	$ (86,178)	219,408	$ 10,235,570	$ 1,496,807	$ 8,738,762	0.0%	-5.9%	-1.0%
10/9/2002	J7A/B/C - ALPHA/BETA Adrenergic Blockers	$ (95,311)	$ 33,670	$ (61,641)	267,232	$ 5,597,942	$ 922,035	$ 4,675,907	-1.7%	3.7%	-1.3%
++10/9/2002	M9P - Platelet Aggrtegation Inhibitors	$ (247,175)	$ 86,614	$ (160,561)	84,572	$ 8,705,396	$ 2,442,227	$ 6,263,170	-2.8%	3.5%	-2.6%
***10/9/2002	R1M - Loop Diuretics	$ 27,028	$ (20,228)	$ 6,800	268,499	$ 2,602,170	$ 109,164	$ 2,493,006	1.0%	-18.5%	0.3%
12/10/2002	A4D - ACE Inhibitor W/Diuretics	$ (300)	$ (2,302)	$ (2,602)	24,536	$ 786,088	$ 147,663	$ 638,425	0.0%	-1.6%	-0.4%
12/10/2002	A4F - Angiotensin Receptor Blockers w/Diuretics	$ 44,731	$ (9,560)	$ 35,171	30,835	$ 1,674,204	$ 575,378	$ 1,098,827	2.7%	-1.7%	3.2%
++12/10/2002	A4K - Ace Inhibitor w/CCB	$ (19,337)	$ (13,022)	$ (32,358)	20,204	$ 1,239,990	$ 394,042	$ 845,948	-1.6%	-3.3%	-3.8%
12/10/2002	C4N - Thiazolidenediones	$ (1,359,761)	$ 2,072,930	$ 713,169	83,128	$ 10,288,250	$ 2,917,608	$ 7,370,642	-13.2%	71.0%	9.7%
12/10/2002	H3F - Triptans	$ 283,488	$ (83,153)	$ 200,335	20,647	$ 3,118,487	$ 922,647	$ 2,195,841	9.1%	-9.0%	9.1%
12/10/2002	J5D - Beta Agonists	$ 1,868,973	$ (664,114)	$ 1,204,859	336,226	$ 13,093,264	$ 3,541,474	$ 9,551,790	14.3%	-18.8%	12.6%
***12/10/2002	M4E - Statins	$ (216,561)	$ (124,418)	$ (340,978)	263,731	$ 23,951,246	$ 7,022,609	$ 16,928,637	-0.9%	-1.8%	-2.0%
12/10/2002	P5A - Inhaled Glucocorticoids	$ 238,929	$ (138,318)	$ 100,611	60,964	$ 6,260,304	$ 1,874,529	$ 4,385,775	3.8%	-7.4%	2.3%
*12/10/2002	Q7E/P - Nasal Anti-histamine/Anti-inflammatory Ster	$ (31,402)	$ 26,116	$ (5,285)	81,538	$ 4,796,707	$ 2,232,028	$ 2,564,680	-0.7%	1.2%	-0.2%
*12/10/2002	Q9B - Benign Prostatic Hypertrophy Agents	$ (4,157)	$ (390)	$ (4,547)	26,713	$ 1,675,861	$ 541,518	$ 1,134,343	-0.2%	-0.1%	-0.4%
***12/10/2002	Z4B - Leukotriene Receptor Antagonists	$ (18,630)	$ (1,943)	$ (20,573)	92,629	$ 7,266,881	$ 1,774,259	$ 5,492,622	-0.3%	-0.1%	-0.4%
1/7/2003	A4F - Angiotensin Receptor Blockers	$ (170,665)	$ 175,766	$ 5,100	40,028	$ 1,717,888	$ 518,278	$ 1,199,610	-9.9%	33.9%	0.4%
***1/7/2003	W1D - Macrolides	$ (42,428)	$ (2,684)	$ (45,112)	140,688	$ 5,774,135	$ 1,150,613	$ 4,623,522	-0.7%	-0.2%	-1.0%
*1/7/2003	W1Q - Fluoroquinolones	$ 80,312	$ (46,835)	$ 33,477	87,305	$ 5,964,636	$ 2,224,411	$ 3,740,225	1.3%	-2.1%	0.9%
1/7/2003	W1W/X/Y - Cephalosporins	$ 901,394	$ (450,672)	$ 450,722	148,068	$ 5,174,127	$ 1,117,118	$ 4,057,009	17.4%	-40.3%	11.1%
1/7/2003	W3B - Antifungals	$ 720,430	$ (312,064)	$ 408,367	34,720	$ 2,827,830	$ 792,432	$ 2,035,398	25.5%	-39.4%	20.1%
2/26/2003	H6J - Antiemetic/Antivertigo Agents	$ 91,931	$ (21,608)	$ 70,323	6,006	$ 2,461,586	$ 1,066,644	$ 1,394,942	3.7%	-2.0%	5.0%
***2/26/2003	M9K - Heparin and Related Products	$ (379,076)	$ 62,130	$ (316,946)	17,420	$ 2,868,251	$ 376,183	$ 2,492,068	-13.2%	16.5%	-12.7%
++2/26/2003	P4L - SERM's/Bone Resorption Suppression Agents	$ (54,168)	$ (112,555)	$ (166,723)	113,018	$ 7,280,960	$ 1,712,836	$ 5,568,124	-0.7%	-6.6%	-3.0%
***5/14/2003	C4K - Antidiabetic Agents	$ (16,131)	$ (1,971)	$ (18,102)	150,749	$ 4,724,529	$ 1,107,744	$ 3,616,785	-0.3%	-0.2%	-0.5%
5/14/2003	D7L - Bile Acid Sequestrants	$ 55,319	$ (29,946)	$ 25,373	5,458	$ 382,354	$ 78,074	$ 304,281	14.5%	-38.4%	8.3%
***5/14/2003	H3A - Brand Name Narcotics	$ 665,416	$ (385,518)	$ 279,898	950,794	$ 37,345,690	$ 9,029,868	$ 28,315,823	1.8%	-4.3%	1.0%
5/14/2003	H6H - Skeletal Muscle Relaxants	$ 937,899	$ (556,619)	$ 381,280	171,950	$ 6,916,328	$ 1,137,393	$ 5,778,935	13.6%	-48.9%	6.6%
++5/14/2003	M4E - Fibric Acids	$ (98,679)	$ (123)	$ (98,802)	51,744	$ 2,596,024	$ 686,445	$ 1,909,579	-3.8%	0.0%	-5.2%
5/14/2003	R1A - Urinary Tract Antispasmodic/Anti Incontinenc	$ 681,181	$ (94,578)	$ 586,603	99,451	$ 7,449,965	$ 1,591,629	$ 5,858,336	9.1%	-5.9%	10.0%
7/21/2003	J3A - Smoking Cessation	$ 37,541	$ (8,664)	$ 28,877	8,164	$ 725,455	$ 71,390	$ 654,065	5.2%	-12.1%	4.4%
*7/21/2003	L1B - Systemic Vitamin A Derivatives	$ 4,252	$ (5,583)	$ (1,330)	92	$ 39,917	$ 38,188	$ 1,729	10.7%	-14.6%	-76.9%
*7/21/2003	L5F - Antipsoriatics	$ 20,751	$ (10,923)	$ 9,827	3,452	$ 410,779	$ 144,066	$ 266,714	5.1%	-7.6%	3.7%
***7/21/2003	L9B - topical Vitamin A Derivitives	$ 17,702	$ (31,217)	$ (13,515)	4,348	$ 272,090	$ 95,665	$ 176,425	6.5%	-32.6%	-7.7%
*7/21/2003	N1B - Hematinics	$ (267,654)	$ 102,670	$ (164,984)	9,412	$ 5,722,548	$ 1,310,599	$ 4,411,949	-4.7%	7.8%	-3.7%
7/21/2003	N1C - Leukocyte Stimulants	$ 202,904	$ (27,321)	$ 175,583	764	$ 1,161,282	$ 249,624	$ 911,658	17.5%	-10.9%	19.3%
**7/21/2003	P4B - Bone Formation Stimulating Agents	$ -	$ -	$ -	364	$ 184,198	$ 25,659	$ 158,540	0.0%	0.0%	0.0%
++7/21/2003	Q6G - Miotics/Other intraocular Pressure Reducers	$ (2,057)	$ (80,391)	$ (82,448)	51,348	$ 2,566,857	$ 610,539	$ 1,956,318	-0.1%	-13.2%	-4.2%
++7/21/2003	Q6I - Eye Antibiotic/Corticosteroid Combos	$ 73,469	$ (84,473)	$ (11,004)	4,320	$ 232,597	$ 166,199	$ 66,398	31.6%	-50.8%	-16.6%
***7/21/2003	Q6R - Eye Antihistamines	$ 19,948	$ (2,124)	$ 17,824	6,808	$ 441,779	$ 163,026	$ 278,753	4.5%	-1.3%	6.4%
++7/21/2003	Q6U - Ophthalmic Mast Cell Stabilizers	$ 36,673	$ (43,296)	$ (6,624)	2,416	$ 149,268	$ 66,687	$ 82,580	24.6%	-64.9%	-8.0%
++7/21/2003	Q6W - Ophthalmic Antibiotics	$ 151,168	$ (169,667)	$ (18,499)	33,372	$ 857,643	$ 395,957	$ 461,686	17.6%	-42.8%	-4.0%
***7/21/2003	Q8F/W - Otic Antibiotics	$ (10,342)	$ (32,593)	$ (42,936)	29,248	$ 1,102,343	$ 316,976	$ 785,367	-0.9%	-10.3%	-5.5%
**8/6/2003	D4F - Antiulcer/H.Pylori Agents	$ 11,621	$ (436)	$ 11,185	882	$ 224,258	$ 87,773	$ 136,485	5.2%	-0.5%	8.2%
8/6/2003	Q4F - Vaginal Antimicrobials	$ 168,470	$ (91,785)	$ 76,685	10,086	$ 409,533	$ 163,081	$ 246,452	41.1%	-56.3%	31.1%
*8/6/2003	Q4K - Topical Estrogen Agents	$ (347)	$ (7,006)	$ (7,353)	6,402	$ 364,305	$ 178,704	$ 185,601	-0.1%	-3.9%	-4.0%
8/6/2003	Q5F - Topical Antifungal Agents	$ 334,832	$ (285,697)	$ 49,136	77,142	$ 2,976,506	$ 621,985	$ 2,354,520	11.2%	-45.9%	2.1%
8/6/2003	W5A - Anti-Herpetic Agents	$ 210,266	$ 37,542	$ 247,808	19,572	$ 1,638,384	$ 598,318	$ 1,040,067	12.8%	6.3%	23.8%
****8/6/2003	W5A - Influenza Agents	-	-	-							
****9/17/2003	S3B - NSAIDS/COX II										
TOTAL ALL PDL PROGRAMS		**$ 12,434,379**	**$ (3,524,829)**	**$ 8,909,550**	**4,936,501**	**$ 270,872,141**	**$ 70,104,418**	**$ 200,767,723**	**4.59%**	**-5.03%**	**4.44%**
Totals for Classes With Only Limited Limited Potential For Market Share Changes		$ (136,883)	$ (571,946)	$ (708,829)	2,360,481	$ 115,967,894	$ 29,425,857	$ 86,542,036	-0.12%	-1.94%	-0.82%
Totals for All Classes With Substantial Potential For Change		$ 12,571,262	$ (2,952,883)	$ 9,618,379	2,576,019	$ 154,904,247	$ 40,678,561	$ 114,225,687	8.12%	-7.26%	8.42%
Totals for Classes With Adverse Savings Potential		$ 636,446	$ (1,980,304)	$ (1,343,858)	589,193	$ 37,436,796	$ 11,017,627	$ 26,419,169	1.70%	-17.97%	-5.09%
Totals for Classes With Both Potential For Substantial Change and With A Potential For Positive Savings		$ 11,934,816	$ (972,579)	$ 10,962,237	1,986,827	$ 117,467,451	$ 29,660,934	$ 87,806,517	10.16%	-3.28%	12.48%

Classes With Limited Potential for Change:
* Classes with no non-preferred drugs
** Classes with no preferred drugs
*** Classes with preferred drugs having more than 95 percent of market share at program start
**** Classes with too low volume or too short of an operational period to be evaluated
Classes Starting With Negative Savings Potential
++ Classes where average preferred drug net cost per claim was greater than the average net cost per claim for non-preferred drugs

TABLE 4.3. Year 1 Estimated Annualized Savings Analysis Summary

Indiana Medicaid

Annualized Estimated Savings Analysis Summary - Year 1

Year 1 - Count of Therapeutic Classes	Category of Therapeutic Classes	Jan-02 (Before PDL by 7 months) % Pre-ferred	Sept-03 (End Year 1 of PDL Program) % Preferred	Adjusted Annualized Net Savings Over 1st 12 Months (1st Yr of PDL) (Adjusted Annualized Net Savings minus Fed. Rebate)
52	**TOTAL ALL PDL PROGRAMS**	**75.2%**	**95.8%**	**$8,909,550**
21	Totals for Classes With Only Limited Potential For Market Share Changes (>95%)			($708,829)
6	Classes With all Preferred Drugs (100%)			
22	Totals for Classes with Substantial Potential For Change (<=94%)			$9,618,379
3	Classes with all NonPreferred Drugs (0%)			

TABLE 4.4. Year 2 Estimated Annualized Savings Analysis Summary

Indiana Medicaid

Annualized Estimated Savings Analysis Summary - Year 2

Year 2 - Count of Therapeutic Classes	Category of Therapeutic Classes	Sept/Oct 04 (End Year 2 of PDL Program) % Preferred	Adjusted Annualized Net Savings Over 2nd 12 Months (2nd Yr of PDL) (Adjusted Annualized Net Savings minus Fed. Rebate)	Annualized Estimated Amount Paid Total Rebates. Contains both state and Federal
54	**TOTAL ALL PDL PROGRAMS**	**93.8%**	**$1,128,929**	**$298,601,311**
22	Totals for Classes With Only Limited Potential For Market Share Changes (>95%)		$1,036,467	$195,966,447
6	Classes With all Preferred Drugs (100%)		$478,337	$71,857,023
21	Totals for Classes with Substantial Potential For Change (<=94%)		($199,404)	$298,601,311
5	Classes with all NonPreferred Drugs (0%)		$127,850	$13,245,624

TABLE 4.5. Year 2 Estimated Annualized Savings Analysis – Detailed Report by PDL Class

Original Implementation Date	2nd Year Change Date	Ther Class	PREFERRED DRUGS	Jan-02 (Before PDL by 7 months) % Preferred	Sept-03 (End Year 1 of PDL Program) % Preferred	Adjusted Annualized Net Savings Over 1st 12 Months (1st Yr of PDL) (Adjusted Annualized Net Savings minus Fed. Rebate)	Sept/Oct 04 (End Year 2 of PDL Program) % Preferred	Adjusted Annualized Net Savings Over 2nd 12 Months (2nd Yr of PDL) (Adjusted Annualized Net Savings minus Fed. Rebate)	Annualized Amount Paid Total Prior to Rebates	% Preferred Change from Year 1 to Year 2 (negative means lost preferred market share from Year 1)
Aug-02	Oct03, Jun04	Z2A	Z2A - Non-Sedating Antihistamines	24.3%	93.7%	(766,838.25)	94.1%	$2,263,851	$12,792,012	0.4%
Sep-02	Oct03, Jul04	A4D	A4D - ACE Inhibitor	33.1%	98.5%	51,543.55	97.5%	$63,051	$4,487,225	-1.0%
	Sep03, Apr04, Jul04	D4K	D4K - Proton Pump Inhibitors	34.9%	82.4%	6,214,934.91	73.7%	($567,862)	$27,441,018	-8.8%
Oct-02		J7ABC	J7A/B/C - ALPHA/BETA Adrenergic Blockers	94.2%	93.5%	(61,640.62)				
	Mar-04		J7A - ALPHA/BETA Adrenergic Blockers				100.0%	($4,493)	$1,946,456	
	Oct-03		J7C - BETA Adrenergic Blockers				99.9%	($25,723)	$4,251,595	
	--		J7B - ALPHA Adrenergic Blockers				99.5%	$1,777	$196,361	6.3%
	--	A9A	A9A - Calcium Channel Blockers	94.0%	97.6%	(86,178.42)	98.2%	($29,766)	$10,546,741	0.5%
	--	R1M	R1M - Loop Diuretics	93.1%	99.0%	6,799.96	99.8%	($4,197)	$2,092,918	0.8%
	--	M9P	M9P - Platelet Aggregation Inhibitors	90.1%	100.0%	(160,561.02)	98.4%	($13,781)	$12,192,138	-1.7%
Dec-02	Oct-03	C4N	C4N - Thiazolidenediones	52.5%	90.1%	713,168.64	98.7%	($121,660)	$10,005,660	8.7%
	Jul-04	A4D	A4D - ACE Inhibitor W/Diuretics	21.8%	90.0%	(2,602.00)	87.8%	$1,778	$474,777	-2.3%
	Oct-03	A4F	A4F - Angiotensin Receptor Blockers w/Diuretics	50.7%	95.0%	35,170.70	93.1%	$8,798	$1,713,257	-1.9%
	Oct-03	A4K	A4K - Ace Inhibitor w/CCB	95.2%	99.0%	(32,358.44)	100.0%	$1,984	$1,379,662	1.0%
	Oct03,Mar04 May04	M4E	M4E - Statins	99.0%	99.6%	(340,978.41)	100.0%	($25,315)	$27,053,472	0.4%
	Apr-04	H3F	H3F - Triptans	56.1%	93.4%	200,335.05	92.2%	($10,884)	$2,310,830	-1.2%
	Oct03, Jul04	Q9B	Q9B - Benign Prostatic Hypertrophy Agents	100.0%	98.9%	(4,546.86)	98.8%	($691)	$1,808,520	-0.1%
	Oct03, Apr04	J5D	J5D - Beta Agonists	85.4%	96.0%	1,204,858.72	95.2%	$296,897	$9,828,446	-0.8%
	--	P5A	P5A - Inhaled Glucocorticoids	77.5%	97.7%	100,611.16	93.1%	$3,897	$6,609,036	-4.6%
	Apr-04	Q7E/P	Q7E/P - Nasal Anti-histamine/Anti-inflammatory Steroids	100.0%	100.0%	(5,285.25)	97.5%	($3,718)	$4,410,943	-2.5%
	--	Z4B	Z4B - Leukotriene Receptor Antagonists	99.8%	99.9%	(20,573.18)	100.0%	$476,326	$32,682,425	0.1%
Jan-03	Mar-04	A4F	A4F - Angiotensin Receptor Blockers	45.7%	88.5%	5,100.34	85.8%	($1,146)	$1,983,049	-2.7%
	May-04	W1W/X/Y	W1W/X/Y - Cephalosporins	71.7%	99.4%	450,721.61				
			W1W - Cephalosporins				99.8%	($776)	$1,121,164	
			W1X - 2nd Gen Cephalosporins				96.9%	$21,949	$605,519	
			W1Y - 3rd Gen Cephalosporins				76.3%	($39,268)	$2,818,778	-8.3%
	--	W1D	W1D - Macrolides	99.7%	100.0%	(45,111.79)	96.7%	($31,765)	$4,704,570	-3.3%
	Oct03, Sep04	W1Q	W1Q - Fluoroquinolones	100.0%	100.0%	33,477.28	97.9%	($213,557)	$6,388,476	-2.1%
	Apr-04	W3B	W3B - Antifungals	87.4%	94.7%	408,366.70	92.5%	($1,910,968)	$2,530,547	-2.2%
Feb-03	Oct03, Jul04	H6J	H6J - Antiemetic/Antivertigo Agents	96.2%	99.0%	70,323.08	98.4%	($68,242)	$3,404,555	-0.6%
	--	M9K	M9K - Heparin and Related Products	92.3%	89.0%	(316,946.25)	99.8%	$1,520,082	$3,346,150	10.7%
	Jul-04	P4L	P4L - SERM's/Bone Resorption Suppression Agents	62.5%	95.6%	(166,722.99)	93.4%	($12,038)	$7,837,621	-2.2%
May-03	Oct03, Jul04	C4K/L/M	C4K/L/M - Antidiabetic Agents	99.1%	99.9%	(18,101.69)	98.8%	($102,582)	$7,096,763	-1.1%
	--	D7L	D7L - Bile Acid Sequestrants	50.6%	71.2%	25,373.09	72.2%	$14,737	$250,538	1.0%
	Apr-04	H3A	H3A - Brand Name Narcotics	89.3%	98.1%	279,897.57	98.4%	($330,671)	$36,088,507	0.3%
	--	H6H	H6H - Skeletal Muscle Relaxants	54.6%	95.6%	381,280.18	93.7%	($73,697)	$4,176,686	-1.9%
	--	M4E	M4E - Fibric Acids	90.9%	95.4%	(98,801.99)	95.2%	$43,340	$2,306,332	-0.2%
	Mar-04	R1A	R1A - Urinary Tract Antispasmodic/Anti Incontinence Agent	75.7%	98.3%	586,603.33	97.7%	($44,670)	$6,166,399	-0.6%
Jul-03	--	J3A	J3A - Smoking Cessation	69.8%	85.1%	28,877.34	84.8%	($9,744)	$798,560	-0.4%
	Oct03, Jul04	L1B	L1B - Systemic Vit A Derivatives	79.0%	81.8%	(1,330.08)				
		L9B	L9B - Topical Vitamin A Derivatives	97.9%	99.3%	(13,515.48)				
		L1B/5H/9B	L1B/L5H/L9B - Acne Agents (Age 25 and under)				88.8%	$19,305	$705,976	
		L1B/5H/9B	L1B/L5H/L9B - Acne Agents (over 25)				0.0%	($75,700)	$699,809	-1.7%
	Jul-04	L5F, L1A	L5F - Antipsoriatics	55.1%	62.3%	9,827.40	100.0%	($7,869)	$483,398	37.7%
	--	N1B	N1B - Hematinics	100.0%	93.8%	(164,984.36)	100.0%	$42,735	$7,654,848	6.2%
	--	N1C	N1C - Leukocyte Stimulants	80.0%	95.7%	175,583.46	83.9%	($18,367)	$1,252,066	-11.8%
	--	P4B	P4B - Bone Formation Stimulating Agents	0.0%	0.0%	$0	0.0%	$0	$631,913	0.0%
	Mar04, Apr04, Jul04	Q6G	Q6G - Miotics/Other intraocular Pressure Reducers	64.7%	75.5%	(82,448.16)	79.6%	($6,787)	$2,565,907	4.1%
	--	Q6I	Q6I - Eye Antibiotic/Corticosteroid Combos	14.4%	70.4%	(11,003.97)	76.0%	($3,958)	$91,520	5.6%
	Jul-04	Q6R	Q6R - Eye Antihistamines	99.8%	100.0%	17,824.12	98.9%	($3,696)	$300,017	-1.1%
	Oct-03	Q6U	Q6U - Ophthalmic Mast Cell Stabilizers	20.7%	40.7%	(6,623.87)	42.4%	($366)	$128,023	1.7%
	Oct03, May04	Q6W	Q6W - Ophthalmic Antibiotics	94.3%	83.7%	(18,499.42)	98.2%	($101,146)	$682,031	14.5%
	May-04	Q8W	Q8F/W - Otic Antibiotics	97.6%	97.9%	(42,935.95)	99.2%	$33,215	$942,401	1.3%
Aug-03	--	D4F	D4F- Anti-ulcer/H.Pylori Agents			11,185.20	0.0%	$3,659	$21,614	0.0%
	--	Q4F	Q4F - Vaginal Antimicrobials	8.7%	59.3%	76,684.93	67.1%	($403)	$58,480	7.8%
	Apr-04	Q4K	Q4K - Topical Estrogen Agents	100.0%	100.0%	(7,353.26)	82.0%	($2,350)	$215,240	-18.0%
	May-04	Q5F	Q5F - Topical Antifungal Agents	64.0%	92.6%	49,135.59	83.6%	$18,217	$2,150,110	-9.1%
	Oct-03	W5A	W5A - Anti-Herpetic Agents	41.7%	51.6%	247,807.66				
	Apr-04	W5A	W5A - Influenza Agents	0.0%	0.0%	0.00				
		W5A/H6A	W5A - Anti-Herpetic & Influenza Agents				96.0%	($33,673)	$1,621,203	44.4%
Sep-03	Jul-04	S2B	S2B - Cox II's	0.0%	0.0%		0.0%	$199,691	$11,892,289	0.0%
May-04	May-04	R1H	R1H - Inspra (Step Edit: Requires prev.tx w/ spironolactone	N/A	N/A		100.0%	($5,031)	$656,763	
Total		52	**TOTAL ALL PDL PROGRAMS**	**75.2%**	**95.8%**	**$8,909,550**	**93.8%**	**$1,128,929**	**$298,601,311**	**1.1%**
			Totals for Classes With Only Limited Potential For Market Share Changes (>95%)			($708,829)		$1,159,285	$209,868,834	
			Totals for Classes with Substantial Potential For Change (<94%)			$9,618,379		$1,128,929	$298,601,311	

Results by Therapeutic Class

The ACS Market Share Change Methodology generated data that enabled analysis of the relative performance of individual therapeutic classes within the preferred drug list (see Tables 4.1 and 4.4).

This section summarizes the market share changes and annualized financial performance of each therapeutic class, and offers comments to explain some of the dynamics that affected performance.

The summaries are grouped according to several scenarios of observed payment and net savings or by three programmatic features that constrained opportunities for change. In the discussion below, the classes are categorized primarily by the circumstances that existed at the time the preferred drug list was implemented.

Generally, the preferred drug market share had stabilized by the end of Year 2 of the PDL program and there were no large market shifts from 6-months after implementation of each class (end of Year 1) through to the end of Year 2. Some classes changed slightly over time. The majority of classes that *did* show market share changes reverted back toward non-preferred agents. Variations in overall savings performance that occurred during Year 2 were largely due to changes in unit rebate amounts or pricing changes for one or more medications in the class.

Sometimes more expensive PDL drugs were chosen for clinical reasons, based on anticipation of better outcomes. Additionally, some increase in expenditures occurred due to unanticipated rebate or product price changes occurring after the selection of preferred drugs.

Some performance changes were related to quantity or age limits that were being rolled out throughout month 12 – 24 post-implementation. Changes due to quantity or age limits will need additional evaluation to determine their success upon either decreasing inappropriate utilization or effecting net savings after federal rebates. Additional evaluation is needed because limits had not been instituted long enough for an evaluation period and were not a part of this study. This section of the study involved evaluation of market share changes and associated net savings.

In general, savings from implementing a PDL program can occur several ways:

- Savings from starting new users on preferred agents
- Savings from switching users from non-preferred to preferred agents
- Reoccurring savings based on a previous change (residuals)
- Offsetting revenue increases from rebates
- Reduction of unneeded prescriptions

Table 4.4 also shows the preferred drug market share changes by PDL class. In summary, the scenarios used in the analysis with the number of classes covered were:

1. Classes with Positive Net Savings (PDL program noted savings even if CMS rebates were reduced)
2. Classes with Negative Net Savings (PDL program noted cost increases due to shifts in market share)
3. Classes with Zero Savings (PDL program noted break even with prior years)
4. Classes Where Preferred Drug Share Exceeded 95% of all Claims in Class at Program Start (22 classes in Year 1; 21 classes in Year 2).
5. Classes with All Preferred Drugs (6 classes in Year 1; 6 classes in Year 2).
6. Classes with No Preferred Drugs, Only Nonpreferred (3 classes in Year 1; 4 classes in Year 5).

The savings produced by the first scenario was the most desirable to a State Medicaid program because the State's savings were up-front in the form of payment reductions. Up-front payment reductions would be more desirable than paying out more for medications and then waiting several months for the benefit in the form of increased rebate payments. The last three scenarios would appear to offer limited opportunity for savings or losses due to market share shifting from implementing a PDL program. As described below, there were changes among individual drugs in those classes that had an impact on net savings.

1-3. Classes with Positive Net Savings, Negative Net Savings and Zero Changes.

Count of Classes		Adjusted Annualized Net Savings Over 2nd 12 Months (2nd Yr of PDL)	Annualized Amount Paid Total
36	Classes with Negative Net Savings (Costs more)	-$3,906,560	$197,930,422
17	Classes with Positive Net Savings	$5,035,489	$100,038,975
1	Classes with Zero Net Savings (Break Even)	$0	$631,913

4. Classes Where Preferred Drugs Had Over 95% of Market Share At Program Start

Year 1 of PDL Program

A9A – CCBs (Calcium Channel Blockers)
R1M – Loop Diuretics
M4E -- Statins
Z4B – Leukotriene Receptor Antagonists
W1D – Macrolide Antibiotics
M9K – Heparin
C4K – Anti-Diabetic Drugs
H3A – Brand name Narcotics
L9B – Topical Vitamin A Derivatives
Q6R – Eye Antihistamines
Q6F/W – Otic Antibiotics

Year 2 of PDL Program

Therapeutic Class	Jan-02 (Before PDL by 7 months)	Sept-03 (End Year 1 of PDL Program)	Adjusted Annualized Net Savings Over 1st 12 Months (1st Yr of PDL)	Sept/Oct 04 (End Year 2 of PDL Program)	Adjusted Annualized Net Savings Over 2nd 12 Months (2nd Yr of PDL)	Annualized Amount Paid Total	% Preferred Change Yr1 to Yr2
A4D - ACE Inhibitor	33.1%	98.5%	51,543.55	97.5%	$63,051	$4,487,225	-1.0%
J7A/B/C - ALPHA/BETA Adrenergic Blockers	94.2%	93.5%	(61,640.62)	99.8%			
J7C - BETA Adrenergic Blockers				99.9%	($25,723)	$4,251,595	
J7B - ALPHA Adrenergic Blockers				99.5%	$1,777	$196,361	6.3%
A9A - Calcium Channel Blockers	94.0%	97.6%	(86,178.42)	98.2%	($29,766)	$10,546,741	0.5%
R1M - Loop Diuretics	93.1%	99.0%	6,799.96	99.8%	($4,197)	$2,092,918	0.8%
M9P - Platelet Aggregation Inhibitors	90.1%	100.0%	(160,561.02)	98.4%	($13,781)	$12,192,138	-1.7%
C4N - Thiazolidinediones	52.5%	90.1%	713,168.64	98.7%	($121,660)	$10,005,660	8.7%
Q9B - Benign Prostatic Hypertrophy Agents	100.0%	98.9%	(4,546.86)	98.8%	($691)	$1,808,520	-0.1%
Q7E/P - Nasal Anti-histamine/Anti-inflammatory Steroids	100.0%	100.0%	(5,285.25)	97.5%	($3,718)	$4,410,943	-2.5%
W1W - Cephalosporins				99.8%	($776)	$1,121,164	
W1X - 2nd Gen Cephalosporins				96.9%	$21,949	$605,519	
W1D - Macrolides	99.7%	100.0%	(45,111.79)	96.7%	($31,765)	$4,704,570	-3.3%
W1Q - Fluoroquinolones	100.0%	100.0%	33,477.28	97.9%	($213,557)	$6,388,476	-2.1%
H6J - Antiemetic/Antivertigo Agents	96.2%	99.0%	70,323.08	98.4%	($68,242)	$3,404,555	-0.6%
M9K - Heparin and Related Products	92.3%	89.0%	(316,946.25)	99.8%	$1,520,082	$3,346,150	10.7%
C4K/L/M - Antidiabetic Agents	99.1%	99.9%	(18,101.69)	98.8%	($102,582)	$7,096,763	-1.1%
H3A - Brand Name Narcotics	89.3%	98.1%	279,897.57	98.4%	($330,671)	$36,088,507	0.3%
M4E - Fibric Acids	90.9%	95.4%	(98,801.99)	95.2%	$43,340	$2,306,332	-0.2%
R1A - Urinary Tract Antispasmodic/Anti Incontinence Agent	75.7%	98.3%	586,603.33	97.7%	($44,670)	$6,166,399	-0.6%
Q6R - Eye Antihistamines	99.8%	100.0%	17,824.12	98.9%	($3,696)	$300,017	-1.1%
Q6W - Ophthalmic Antibiotics	94.3%	83.7%	(18,499.42)	98.2%	($101,146)	$682,031	14.5%
Q8F/W - Otic Antibiotics	97.6%	97.9%	(42,935.95)	99.2%	$33,215	$942,401	1.3%
W5A - Anti-Herpetic & Influenza Agents				96.0%	($33,673)	$1,621,203	44.4%

5. Classes with All Preferred Drugs

Classes with all preferred drugs at the beginning of PDL program implementation (in other words there were no non-preferred drugs in the class) have no opportunity for savings from patients being switched from non-preferred to preferred agents.

Year 1 of PDL Program

Q7P/P7E – Nasal Anti-Inflammatory Steroids (100% Preferred Year 1 to 97.5% Year 2)
Q9B – Benign Prostatic Hypertrophy Agents (100% Preferred Year 1 to 98.8% Year 2)
W1Q – Fluoroquinolones (100% Preferred Year 1 to 97.9% Year 2)
L1B – Systemic Vitamin A Derivatives (100% Preferred Year 1 to 88.8% Year 2)
N1B – Hematinics (100% Preferred Year 1 and stayed 100.0% in Year 2)
Q4K – Topical Estrogen Agents (100% Preferred Year 1 to 82.0% Year 2)

Year 2 of PDL Program

Therapeutic Class	Jan-02 (Before PDL by 7 months)	Sept-03 (End Year 1 of PDL Program)	Adjusted Annualized Net Savings Over 1st 12 Months (1st Yr of PDL)	Sept/Oct 04 (End Year 2 of PDL Program)	Adjusted Annualized Net Savings Over 2nd 12 Months (2nd Yr of PDL)	Annualized Amount Paid Total	% Preferred Change Yr1 to Yr2
A4K - Ace Inhibitor w/CCB	95.2%	99.0%	(32,358.44)	100.0%	$1,984	$1,379,662	1.0%
M4E - Statins	99.0%	99.6%	(340,978.41)	100.0%	($25,315)	$27,053,472	0.4%
Z4B - Leukotriene Receptor Antagonists	99.8%	99.9%	(20,573.18)	100.0%	$476,326	$32,682,425	0.1%
L5F - Antipsoriatics	55.1%	62.3%	9,827.40	100.0%	($7,869)	$483,398	37.7%
N1B - Hematinics	100.0%	93.8%	(164,984.36)	100.0%	$42,735	$7,654,848	6.2%
R1H - Inspra (Step Edit: Requires prev.tx w/ spironolactone)	N/A	N/A		100.0%	($5,031)	$656,763	

Adjusted Annualized Net Savings Over 2nd 12 Months (2nd Yr of PDL)	Annualized Amount Paid Total
$ 478,337	$71,857,023

6. Classes with No Preferred Drugs

Year 1 of PDL Program

P4B – Bone Formation Stimulating Drugs
D4F – Antiulcer/H. Pylori Drugs

Year 2 of PDL Program

Therapeutic Class	Jan-02 (Before PDL by 7 months)	Sept-03 (End Year 1 of PDL Program)	Adjusted Annualized Net Savings Over 1st 12 Months (1st Yr of PDL)	Sept/Oct 04 (End Year 2 of PDL Program)	Adjusted Annualized Net Savings Over 2nd 12 Months (2nd Yr of PDL)	Annualized Amount Paid Total	% Preferred Change Yr1 to Yr2
L1B/L5H/L9B - Acne Agents (over 25)				0.0%	($75,700)	$699,809	-1.7%
P4B - Bone Formation Stimulating Agents	0.0%	0.0%	$0	0.0%	$0	$631,913	0.0%
D4F- Anti-ulcer/H.Pylori Agents	0.0%	0.0%	11,185.20	0.0%	$3,859	$21,614	0.0%
S2B - Cox II's				0.0%	$199,691	$11,892,289	0.0%

Adjusted Annualized Net Savings Over 2nd 12 Months (2nd Yr of PDL)	Annualized Amount Paid Total
$127,850	$13,245,624

Conclusions on PDL Program Savings

The Indiana Medicaid Preferred Drug List Program as implemented through September 2004 involved 54 therapeutic classes. In year one, the program succeeded in increasing the share of preferred drugs relative to their nonpreferred alternatives from 75.2% in January 2002 to 95.8% by September 2003. In year two, the program succeeded in retaining market share at 93.8% preferred drugs dispensed. The pharmacy net savings resulting from implementing a PDL program were estimated to be between $7.40 to 8.16 million in Year 1, and an additional $380,000 to (-$370,000) in Year 2. Over the two-year period after implementation of the PDL, the overall net pharmacy savings are estimated to be between **$7.03 to $8.53 million**.

The program included several therapeutic classes with very limited opportunities for shifting from nonpreferred to preferred medications. Some of these classes experienced cost increases rather than cost savings because of changes among the preferred medications.
The program also included several classes where the net costs for the preferred medications were greater than the net costs of the nonpreferred drugs. In those classes, the preferred drugs were considered clinically superior and safer than the lower cost drugs in the class. Shifting a prescription from nonpreferred to preferred in those classes increased the net cost.

Given the ability of the PDL program to increase preferred drug market share, the choice of therapeutic classes with opportunities for such shifts and the selection of the most cost-effective drugs as preferred were crucial to fully realizing the potential financial benefits of the preferred drug list. The selected drugs must be clinically appropriate to the needs of the target population and the expected net cost (expected payment amount per claim less expected rebate amount per claim) of preferred drugs must be lower than that of the nonpreferred drugs that they are likely to be replacing. It is necessary to consider both the price paid to pharmacies and the federal rebates received from manufacturers in assessing relative net costs. If the average net cost for preferred drugs in a class is more costly than the nonpreferred drugs, then shifting to preferred drugs increases rather than decreases costs.

To produce substantial savings with a preferred drug list, it is also important to limit the number of drugs deemed as “preferred.” Overly inclusive lists limit savings since they reduce the number of nonpreferred drug prescriptions eligible for change. In addition, the excluded AAAX drugs should be considered as part of the PDL since their percentage of the overall cost continue to climb.

Limitations of the Savings Estimation Methodology

There is nothing inherent in the design of a preferred drug program that causes overall utilization increases. The program does not promote the new use of particular drugs (i.e., a PDL is not intended to encourage the use of a drug that has not been previously in use)

rather an intervention occurs when a prescription for a nonpreferred drug is being processed. At this point in time, the nonpreferred medication may be dispensed, the prescription may be changed to a preferred medication, or the therapy may be terminated. Thus, there is the intrinsic possibility of some utilization decline in association with a PDL intervention. If there is any decrease in utilization, the calculated savings will decline accordingly. If the reduction in utilization is due to reduction of inappropriate utilization by the PDL intervention, then there are real utilization savings for the State in the form of fewer overall claims. This methodology does not adjust the PDL savings estimates to capture such program savings. It is very difficult to discern the extent to which any observed reduction in utilization in a PDL class was due to the intervention or to other factors. Therefore, the estimates presented may underestimate the program savings. Additionally, if prescribing practitioners switch their patients to the preferred drug, or start prescribing the preferred drug before the implementation of each PDL phase, the methodology does not capture the potential savings.